

EXHIBIT 49

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION

This document relates to:
*The County of Summit, Ohio, et al. v. Purdue
Pharma L.P., et al.*
Case No. 18-op-45090

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

**SUMMIT COUNTY AND THE CITY OF AKRON, OHIO PLAINTIFF'S
SUPPLEMENTAL RESPONSES AND OBJECTIONS TO
MANUFACTURER DEFENDANTS' INTERROGATORY
NUMBERS 1, 2, 3, 5, 8, 9, 11, 12, 13, 15, 20, 21, 26, 27, 28 & 29**

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure and the Case Management Order in *In re National Prescription Opiate Litigation*, No. 1:17-cv-2804 (Dkt. No. 232), The County of Summit, Ohio and the City of Akron, Ohio ("Plaintiff") hereby responds to Manufacturer Defendants'¹ Interrogatory Nos. 1, 2, 3, 5, 8, 9, 11, 12, 13, 15, 20, 21, 26, 27, 28 & 29 (the "Interrogatories" and, each individually, a "Interrogatory"), as follows:

OBJECTIONS

The following objections apply to each Interrogatory. To the extent that certain specific objections are cited in response to an individual Interrogatory, those specific objections are provided because they are applicable to that specific Interrogatory and are not a waiver of the objections applicable to information falling within the scope of such Interrogatory.

¹ The Manufacturer Defendants are Endo Pharmaceuticals Inc.; Endo Health Solutions Inc.; Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Company Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; and Insys Therapeutics, Inc.

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1. Plaintiff objects to each Interrogatory to the extent they are overly broad, vague, unduly burdensome, seeks information that is not relevant to any party's claim or defense, or seeks to impose obligations or require actions beyond those required by the Rules of Civil Procedure, the ESI Protocol entered in this matter or the Local Rules of the United States District Court of the Northern District of Ohio.

2. Plaintiff objects to each Interrogatory to the extent they seek information restricted from dissemination pursuant to court order, statute, or regulation. Further, Plaintiff's responses to the Interrogatories are not intended to waive, and does not constitute any waiver of, any objection to the admissibility, authenticity, competency or relevance of the information identified.

3. These responses are made solely for the purpose of and in relation to this action. Each answer is given subject to all appropriate objections, which would require the exclusion at trial of any statement contained provided herein. All such objections and the grounds therefore are hereby reserved.

4. The fact that any of the Interrogatories herein may have been answered should not be taken as an admission or a concession of the existence of any facts set forth or assumed by the Interrogatories, or that such answer constitutes evidence of any fact thus set forth or assumed.

5. Plaintiff objects to each Request to the extent Plaintiff has not yet completed its investigation of the facts relating to this action and has not yet completed its preparation for trial. Accordingly, these responses are necessarily limited in nature, and reflect only that information known to Plaintiff at this time.

6. Plaintiff objects to each Interrogatory to the extent they purport to require Plaintiff to provide information that is in the public domain or otherwise available to Manufacturers as easily from other sources as from Plaintiff.

7. Plaintiff objects to each Interrogatory to the extent they purport to state facts, assumptions, or characterizations that are disputed.

8. Plaintiff objects to each Interrogatory to the extent they seek information more appropriately obtained through other methods of discovery.

9. Plaintiff objects to each Interrogatory to the extent that they seek information that is proprietary or confidential or that is protected from discovery as attorney work product and attorney-client communication, information gathered or prepared in anticipation of litigation, the public interest privilege, law enforcement privilege, public official privilege, and/or by any other privilege or immunity from disclosure (collectively, "Privileged Information").

10. Plaintiff objects to each Interrogatory to the extent they seek confidential investigative, personal, or health information in Plaintiff's possession, custody, or control (collectively, "Confidential Information").

11. Whenever in the responses Plaintiff employs the phrase "subject to and without waiving all objections," Plaintiff is responding to the Interrogatory as it may be narrowed by its objections and without waiver of any objection.

12. Any response stating that Plaintiff will produce information shall be deemed followed by the phrase "as are within Plaintiff's possession, custody, or control."

13. Plaintiff objects to each Interrogatory to the extent that they imply the existence of facts or circumstances that do not or did not exist, and to the extent that it states or assumes legal conclusions. In providing these objections and responses, Plaintiff does not admit the factual or legal premise of any Interrogatory.

14. Plaintiff objects to each Interrogatory to the extent they seek information that is not within Plaintiff's possession, custody, or control, seek documents that do not already exist, or

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which purport to require a response by Plaintiff on behalf of an entity or individual other than Plaintiff.

15. Plaintiff reserves the right to supplement, revise, correct, or clarify its responses and objections in the event that additional information becomes available.

16. Plaintiff intends to complete its production by the time agreed upon by the parties for the completion of discovery, or by the date ordered by the Court. Upon request by the requesting party, Plaintiff is willing to meet and confer regarding its responses to the Interrogatories. All final decisions regarding whether any information will be withheld pursuant to any objection shall be made, and notice thereof provided, before the completion of written discovery.

NON-WAIVER

1. Plaintiff's responses are made without waiving its right to object (on the grounds of relevancy, hearsay, materiality, competency or any other ground) to the use of its responses in any subsequent stage or proceeding in this Action or any other action.

2. If Plaintiff, in response to any Interrogatory, inadvertently produces information that is or could be the subject of objections stated herein, such information is not intended to be, nor is it deemed to be, a waiver of the objections with respect to such information produced or withheld.

3. Plaintiff's failure to object to a specific Interrogatory on a particular ground or grounds shall not be construed as a waiver of its rights to object on any additional grounds.

4. Plaintiff responds herein based upon information it has been reasonably able to gather at the time of making these responses. Plaintiff reserves its right to amend and/or to supplement its objections and responses to the Interrogatories, consistent with further investigation and discovery.

SPECIFIC RESPONSES AND OBJECTIONS

Interrogatory No. 1:

Identify each and every doctor or other healthcare provider who Plaintiff alleges participated in “speaker programs” or “speakers’ bureaus” on behalf of or in relation to any Defendant, as alleged in Plaintiff’s Complaint. For each identified doctor or other healthcare provider, please also identify in the response the events or programs that Plaintiff alleges the doctor or other healthcare provider attended or spoke at and identify the amount of payment allegedly provided by each Defendant.

Response:

Plaintiff repeats and reasserts its prior objections and adopts its prior responses to this Interrogatory. Plaintiff objects to this Interrogatory as vague, overly broad, and unduly burdensome to the extent it requests “each and every” doctor or healthcare provider who “participated” in “speaker programs” or “speakers’ bureaus.” Further objecting, Plaintiff objects to this Interrogatory as overly broad and also to the extent it seeks information that is squarely in Defendants’ possession and control. Given the late production of documents by so many Defendants, Plaintiff reserves its right to supplement, modify or amend its answers. Each Defendant has, or should have, records that identify each and every doctor or other healthcare provider who participated in “speaker programs” or “speakers’ bureaus” on behalf of or in relation to the subject Defendant. Defendants thus have far superior access to this information.

Moreover, hundreds of depositions of fact witnesses have been taken of defense witnesses and bellwether Plaintiffs utilizing hundreds of exhibits. The discovery performed to date, including depositions and extensive document productions, provides details of conduct relevant to this response. It is not practicable to specifically identify each and every payment or every speaker or every responsive document. Plaintiffs reserve the right to rely upon and introduce as evidence any

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and all deposition testimony and exhibits addressing this topic. Also, Plaintiff's discovery, document review and investigation are continuing, and it reserves its right to rely upon and introduce further evidence addressing this topic.

Subject to and without waiving all options, Plaintiff includes by way of examples, Plaintiffs supplement their responses as follows:

- From 2008 to 2013, Purdue made payments totaling almost \$231,000 for speaker programs, advisory meetings and travel costs to 11 Advocates appearing on the Purdue funded website, www.inthefaceofpain.com;
- Physicians identified by Insys Therapeutics, Inc. as having received compensation from Insys "for speaking about, endorsing or promoting SUBSYS in the State of Ohio." (See Insys Therapeutics, Inc.'s Responses and Objections to Plaintiff's First Set of Interrogatories);
- Physicians identified by Janssen Pharmaceuticals, Inc., its predecessor companies Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc., and its parent company Johnson & Johnson as having received compensation "for Nucynta IR and Nucynta ER speaker programs." (See Janssen Pharmaceuticals, Inc.'s Responses and Objections to Plaintiff's First Set of Interrogatories);
- Physicians identified through ProPublica as payments publicly disclosed in Ohio from August 2013 until December 2015;
- Sales representatives from each of the Marketing Defendants visited prescribers in Summit County. Sales representatives from Purdue, Teva, Mallinckrodt, and Insys were the most frequent visitors to Summit County prescribers where, according to publicly available data, there were at least 381, 247, 149, and 138 sales visits respectively, between the third quarter of 2013 and 2016. These visits frequently coincided with payments to the prescriber for "promotional speaking," "food and beverage," "consulting," "travel and lodging," "honoraria," and "education." Purdue, Teva, Janssen, Endo, Mallinckrodt and Insys paid Summit County prescribers at least \$135,052 in payments associated with those categories during the time period. See <https://projects.propublica.org/docdollars/>.

Subject to and without waiving objections, Plaintiff further responds:

Name	Title	Event Description	Payment
J. David Haddox	Doctor, Committee Chair of AAPM	A "consensus" statement issued in 1997 endorsing	Undisclosed amount

		opioids to treat chronic pain and claiming the addiction risk to patients was low; presentations and panel discussions.	
Russell Portenoy	Doctor, Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, Consultant to AAPM, spokesperson for Purdue	A "consensus" statement issued in 1997 endorsing opioids to treat chronic pain and claiming the addiction risk to patients was low. A quote on www.inthefaceofpain.com advocating for the need for chronic pain treatment; various speaking engagements, conferences, grants, Continuing Medical Education ("CME") programs and honorariums	>\$373,528
Lynn Webster	Doctor, co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah, spokesperson for Cephalon, Endo and Purdue	Participated in numerous CMEs; honorariums	Over \$2 million
Perry Fine	Doctor, co-chair of APS/AAPM Opioid Guideline Panel, spokesperson for Endo and Johnson & Johnson	Numerous CMEs for Endo and promotional talks for Johnson & Johnson; honorariums	\$32,017 from Johnson & Johnson; at least \$100,000 from others
Scott Fishman	Doctor, served as a board member of APF and president of AAPM	Participated in numerous CMEs; honorariums	> \$10,000
Steven Simon	Doctor at Mid-America Physiatrists	Wrote prescriptions for Subsys and Fentanyl and	> \$200,000 from August 2013 to

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	in Overland Park, Kansas	was a designated paid "speaker" for Insys	December 2015
Robert Yapundich	Neurologist in Hickory, NC	Board member of the Alliance for Patient Access and paid "speaker"	> \$300,000 from 2013 to 2016
Howard Hoffberg	Doctor at Rosen-Hoffberg Rehabilitation and Pain Management Associates in Townson, Maryland	Wrote prescriptions for opioids and received "speaker" fees from Insys, Purdue and Teva	> \$175,000 from 2013 to 2016
Heather Alfonso	Nurse practitioner in Connecticut	Wrote prescriptions for Subsys in exchange for "speaker" fees from Insys.	\$83,000
Jerrold Rosenberg	Doctor in Rhode Island	Wrote prescriptions for Subsys in exchange for "speaker" fees from Insys	> \$188,000
Gordon Freedman	Doctor in New York, New York	Wrote prescriptions for Fentanyl in exchange for "speaker" fees from Insys	> \$100,000 annually
Jeffrey Goldstein	Doctor in New Rochelle, New York	Wrote prescriptions for Fentanyl in exchange for "speaker" fees from Insys	> \$100,000 annually
Todd Schlifstein	Doctor in New York, New York	Wrote prescriptions for Fentanyl in exchange for "speaker" fees from Insys	> \$100,000 annually
Dialecti Voudouris	Doctor in New York, New York	Wrote prescriptions for Fentanyl in exchange for "speaker" fees from Insys	> \$100,000 annually
Alexandru Burducea	Doctor in Little Neck, New York	Wrote prescriptions for Fentanyl in exchange for "speaker" fees from Insys	> \$100,000 annually
Michael Frey	Doctor in Florida	Wrote prescriptions for Subsys in exchange for "speaker" fees from Insys	Unknown at this time
Jeffrey Kesten	Doctor in Boulder, Colorado	Wrote prescriptions for Subsys in exchange for "speaker" fees from Insys	\$294,000

Gordon Freedman	Doctor in White Plains, New York	Wrote prescriptions for Subsys in exchange for "speaker" fees from Insys	\$283,000
Dr. Barry Cole	Psychiatrist in Las Vegas, Nevada and founder and executive director of the American Pain Society	Speaker engagements; honorariums	>\$2,000
Dr. Michael P. Rosenthal	Acting Chief, Division of Family Medicine, Penn Medicine	Numerous speaker conferences; honorariums	>\$25,000
Dr. Seddon Savage	Doctor in New Canaan, Connecticut and former president of the American Pain Society	Statements in e-newsletters	>\$3,000
Dr. David Fishbain		Numerous speaker conferences; CMEs; honorariums; statements in e-newsletters	>\$25,000
Dr. Charles Argoff	Director, Cohn Pain Management Center, NY	Speaker conferences; CMEs; honorariums	>\$25,000
Dr. Steven Stanos	Medical Director of Swedish Pain Services and Medical Director of Occupational Medicine Services at Swedish Health System, WA	Speaker conferences; CMEs; honorariums	>\$25,000
Dr. Katherine Galluzzi		Speaker conferences; CMEs; honorariums	>\$25,000
Dr. Michael Moskowitz		Speaker conferences; CMEs; honorariums	>\$25,000
Dr. Grace Forde	Director of Neurological Services, North Shore Pain Services, NY	Speaker conferences; CMEs; honorariums	>\$25,000

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Pursuant to Federal Rule of Civil Procedure 33(d), Plaintiff identifies the following documents containing relevant information on known payments to individuals and front groups:

ACTAVIS0875243
ACTAVIS0290063
ENDO00000001
ENDO00041232
ENDO00153633
ENDO00444162
ENDO00448666
ENDO00451194
ENDO00662274
ENDO00734730
ENDO00735087
ENDO00735356
ENDO-OPIOID_MDL00996815
ENDO-OPIOID_MDL01605959
ENDO-OPIOID_MDL01607843
ENDO-OPIOID_MDL01622909
ENDO-OPIOID_MDL02284410
ENDO-OPIOID_MDL02285365
ENDO-OPIOID_MDL02954028
ENDO-OPIOID_MDL02954031
ENDO-OPIOID_MDL02954051
ENDO-OPIOID_MDL04754820
ENDO-OPIOID_MDL04857592
ENDO-OPIOID_MDL05578670
ENDO-OPIOID_MDL05579494
ENDO-OPIOID_MDL05968408
ENDO-OPIOID_MDL06234663
ENDO-OPIOID_MDL06235133
ENDO-OPIOID_MDL04755213
ENDO-OPIOID_MDL01504894
EPI000648779
EPI000664121
EPI000664705
EPI000649037
EPI000649100
EPI002453701
HAD_MDL_000067430
JAN00000001
JAN-MS-00723779
JAN-MS-00787658
JAN-MS-00787662
JAN-MS-00788087
JAN-MS-00724227

JAN-MS-00275963
JAN-MS-00928088
JAN-MS-00928090
JAN-MS-00928094
JAN-MS-00928097
JAN-MS-00500135
JAN-MS-00506585
JAN-MS-00506584
JAN-MS-01246061
JAN-MS-01240530
JAN-MS-01240620
JAN-MS-01239389
JAN-MS-00503729
JAN-MS-01245171
JAN-MS-01235809
JAN-MS-00275828
JAN-MS-00275814
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PPLP003476848
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PPLPC036000061550
PPLPC036000147128
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PPLPC031000517249
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PPLCP012000045701
PKY180961480
PKY180947135
PKY180785676
PKY180507584
PKY180787071
PKY180470186
PKY180790274
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PKY180784295
PKY180789974
PKY180785481
PKY180572966
PKY180476707
PKY180452310
PKY180359545
PKY180622462
PKY180785211
PKY180784205
PKY180958798
PKY180671526
PKY180246201
PKY180788740
PKY180955343
PKY180515243
PKY180312563
PKY180958896
PKY180784158
PKY180279026
PKY182481437
PKY180779494
PKY180193998
PKY180606599
PKY181775488
PKY180960325
PKY181948251
PKY181944110
PKY181955637
PKY182565361
PKY180606224
PKY180958852
PURCHI-000004624
RP_000221-000741
TEVA_MDL_A_01850104
TEVA_MDL_A_01850482

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TEVA_MDL_A_01850944
TEVA_MDL_A_01854966
TEVA_MDL_A_00835446
TEVA_MDL_A_01852753
TEVA_MDL_A_01088845
TEVA_MDL_A_01088810
TEVA_MDL_A_09741141
APS-MDL00000001
CHI_001208242
CHI_000371635
CHI_001208232
CHI_001207857
CHI_001207836
CHI_001207848
CHI_002298574
CHI_001208505
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CHI_000928503
CHI_000929378
CHI_000930595
CHI_001173523
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CHI_001193789
CHI_000430399
CHI_000434932
CHI_000433583
CHI_001030690
CHI_001164916
CHI_001208252
CHI_001164930
CHI_001164934
CHI_001216588
CHI_001026888
CHI_000437043
CHI_001213322
CHI_001164782
CHI_001213714
CHI_001214142
CHI_001212744
CHI_001208249
CHI_000544147

NHPCO_00004
PLTF_2804_000001465 – PLTF_2804_000003675

For purposes of illustration and by way of example, Plaintiff responds as follows with regard to the Teva-related Defendants:

Cephalon and/or Teva paid doctors to act as speakers in their “speaker programs” and/or “speakers’ bureaus” to promote their opioid products, including speaking and promoting those products for off-label use and without adequately disclosing the risks associated with those products including the risks of misuse, addiction and diversion. Cephalon and/or Teva paid these doctors for training associated with these speakers’ programs and/or bureaus and to speak to doctors and other healthcare providers regarding their opioid products. Such payments either were made directly by Cephalon and/or Teva, or indirectly through patient advocacy organizations or front groups which in turn would retain Cephalon and/or Teva’s trained speakers and pay them out of the funds provided to such organizations and groups. *See, e.g.*, 2/1/19 Beckhardt Dep., and Exh. 25 (TEVA_MDL_A_01174115 - TEVA_MDL_A_01174147); Exh. 26 (TEVA_MDL_A_01089593 - TEVA_MDL_A_01089596); Exh. 29 (TEVA_MDL_A_0189587 - TEVA_MDL_A_0189588).

Cephalon and/or Teva also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Cephalon and/or Teva and other Manufacturer Defendants, these “Front Groups” – which include, but are not limited to, the American Pain Foundation (“APF”) and the American Academy of Pain Medicine (“AAPM”) as detailed below – generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. The evidence did not support these guidelines, materials, and programs at the time they were created,

and the scientific evidence does not support them today. Indeed, they stand in marked contrast to the 2016 CDC Guideline.

Cephalon and/or Teva utilized multiple Front Groups. Several of the most prominent are described below, but there are many others, including the American Pain Society (“APS”), American Geriatrics Society (“AGS”), the Federation of State Medical Boards (“FSMB”), American Chronic Pain Association (“ACPA”), the Center for Practical Bioethics (“CPB”), the U.S. Pain Foundation (“USPF”) and the Pain & Policy Studies Group (“PPSG”). *See generally*, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep’t of Health and Human Servs. (May 5, 2015). Organizations, including the U.S. Senate Finance Committee, began to investigate the APF to determine the links, financial and otherwise, between the organization and the opioid industry. The investigation revealed that APF received 90 percent of its funding from the drug and medical-device industry, and “its guides for patients, journalists and policymakers had played down the risks associated with opioid painkillers while exaggerating the benefits from the drugs.” Within days, APF dissolved “due to irreparable economic circumstances.”

Another front group for Cephalon and/or Teva was the AAPM. With the assistance, prompting, involvement, and funding of Cephalon and/or Teva, along with other opioid manufacturers, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Cephalon and/or Teva’s deceptive marketing of chronic opioid therapy. AAPM received substantial funding from opioid manufacturers.

Examples of documents reflecting responsive information concerning the payments to Cephalon and/or Teva speakers and direct payments can be found at:

- TEVA_MDL_A_10029040 - TEVA_MDL_A_10029045
- TEVA_MDL_A_07116813 - TEVA_MDL_A_07116816
- TEVA_MDL_A_09068993 - TEVA_MDL_A_09068994

- TEVA_MDL_A_01399870 - TEVA_MDL_A_01399872
- TEVA_MDL_A_13583363 - TEVA_MDL_A_13583364
- TEVA_MDL_A_07546996 - TEVA_MDL_A_07547019
- TEVA_MDL_A_00978599 - TEVA_MDL_A_00978601
- TEVA_MDL_A_00784866
- TEVA_MDL_A_03413816
- TEVA_MDL_A_02199962
- TEVA_MDL_A_07116816

With respect to Endo, Plaintiff states as follows:

As part of the post-launch plan for Opana ER, Endo introduced a Promotional Speakers Program to support the new product. The objective of the program was to “educate physicians on the benefits and proper use of Oxymorphone” and to “encourage trial of Oxymorphone with prescribers of long acting opioids.” ENDO-CHI_LIT-00551008. The plan was to hold a “series of promotional meetings with high prescribers of strong opioids.” *Id.* According to a market update report from October 2006, 15 health care providers were trained as speakers and 65 additional health care providers signed up for programs slated to run from October 27-29, 2006. ENDO-CHI_LIT-00547005.

The following year, 2007, saw 4,630 attendees participate in the speaker program. EPI000300652. Endo determined that the return on investment in these programs turned positive 8-12 weeks after the program. *Id.* Cognizant of the high cost per attendee, Endo sought to reformat its program to focus on a patient case format, and target other health care professionals such as nurses and physician assistants, amongst other changes. *Id.*

By 2009, Endo developed three different speaker programs: a Field Driven Speaker’s Bureau, a Regional Opana Prescriber Education Program (“ROPE”), and a Faculty Forum. ENDO-CHI_LIT-00166206. Through a variety of peer-to-peer formats, the goal was to increase awareness and clinical discussion of Opana ER as a preferred therapy to manage the complexities of pain. ENDO-CHI_LIT-00023245. The Field Driven events were regional in nature and targeted markets

of greatest potential. *Id.* Internal projections anticipated approximately 21,000 attendees. *Id.* According to the 2009-2013 Opana Brand Tactical Plan, the estimated investment in the program was \$10 million dollars. *Id.*

The ROPE speaker events were fewer in number but larger events generally, with anticipated attendance of 150 healthcare professionals or more. ENDO-CHI_LIT-00023245. The goal of this program was to increase awareness and clinical discussion of Opana ER as a preferred therapy to manage the complexities of pain. *Id.* The content of ROPE events would revolve around case study slide sets and focus on converting patients to Opana ER. *Id.* The initial plan for this speaker series called for 10 events with an estimated budget of \$593,525. *Id.*

The Faculty Forum series supported Endo's trained speakers. These forums were tailored by local sales reps according to their local territory needs, leading to a variety of meal programs, roundtable discussions or teleconferences. EPI000300652. These events included speaker trainings and targeted field events. ENDO-CHI_LIT-00032734. Endo invested \$3,816,576 in the series and launched the initiative in 2008. EPI000300652. Results showed that 260 speakers were trained in 2008, 1105 programs were completed and 5,200 healthcare providers attended. ENDO-CHI_LIT- 00062030. In 2008, approximately \$6 million was invested in the Faculty Forum speaker program. *Id.* The following year Endo dedicated \$6.4 million to the Faculty Forum program. ENDO-CHI_LIT-00023297. There were 1,000 programs planned for 2009 with 159 opinion leaders trained and 55 additional hcp's scheduled for training. ENDO-CHI_LIT-00062030. Many KOLs came on board as speakers and participated as trainers and speakers in the various speaker programs.

In May 2013, following the FDA's denial of Endo's Citizen Petition, Endo cancelled all remaining promotional speaker programs. ENDO-OR-CID-01330991. According to meeting

minutes from a 2013 Pain Business Unit meeting held at the end of 2013, no speaker programs were scheduled for 2014. EPI000925433 at *34.

Endo understood the importance and influence of KOLs to promote the use of opioids generally, and early on began developing influence maps of regional and local KOLs to support EN3202, as reflected in a January 2004 Monthly Business Report. ENDO-CHI_LIT-00552983. This was later integrated into Endo's strategy of "Building Champions" for Opana ER. ENDO-OPIOID_MDL-00848258. The goal was to "understand who and where the pain medicine thought leaders are"; engage national thought leaders in oxycodone clinical studies, as advisors, as speakers"; and "utilize national advocates to reach regional and local thought leaders. *Id.*

Cultivating Opana advocates and KOLs to encourage adoption of Opana ER's broader use of opioids to treat chronic pain featured prominently in Endo's pre-launch planning for the Opana franchise. Pre-launch, Endo devised a program to develop "Opana Champions." END00000923. "Champions" would be a part of clinical advisory meetings, marketing advisory boards and promotional breakfast meetings." *Id.*

Periodically, Endo would rank KOLs, referring to it internally as a KOL mapping project. ENDO-OPIOID_MDL-01725812. The project involved determining the KOL's overall impact and assigning them to different categories. Endo examined whether their impact was regional or national in nature, the amount of dispersion across states and the number of people nominating the KOL for their place on the KOL mapping project. ENDO-OPIOID_MDL-01725813. Below are the categories and criteria as identified by Endo in 2007:

Criteria	Concentration	Direct Nominations
National High	Greater than 10 dispersed States	15 or more
National Low	Less than 10 dispersed States	9 or more

Regional High	States closely concentrated	8 or more
Regional low	States closely concentrated	Less than 8
Local High	80% of nominations within 50 miles	5 or more
Local Low		Less than 5

Overall, the mapping project allowed Endo to identify the Top 200 KOLs for the Opana.

Endo utilized KOLs in a variety of functions supporting Opana. KOL targets were defined as “physicians who are research focused, national level influence, speakers and research publishers in the medical community.” ENDO-OPIOID_MDL-00627335. Internally, these physicians were referred to as KOLs, or Therapeutic Experts (“TE”). ENDO-OPIOID_MDL-00665227. Members of the Clinical Affairs department, internally referred to as Clinical Affairs Managers (“CAMs”), were responsible for identifying and building “effective working relationships with regional and national TEs in Endo’s area of therapeutic interest.” ENDO-CHI_LIT-00237750. In 2008, Endo identified 674 TEs by topic: 187 experts in osteoarthritis, 128 experts in migraine/neuroscience, and 359 Chronic Pain and Moderate-to-Severe-Chronic Pain experts. *Id.* In 2012, Endo reorganized the department and the former CAMs were retitled to Medical Science Liaisons (“MSLs”). However, the MSLs assignments remained the same as before, including communicating with and developing Endo’s KOL relationships. *Id.*

KOLs and TEs participated in marketing panels, pain task forces and speaking engagements. ENDO-CHI_LIT-00547230, ENDO-CHI_LIT-00217549. They also developed materials supportive of the use of long-acting opioids generally. A 2008 Clinical Affairs presentation listed the following examples of development initiatives with Endo’s KOLs: “Portenoy/Fine *Clinical Guide to Opioid Analgesia* handbook”; “Dworkin – IASP closed roundtable/publications on new data/developments in Neuropathic Pain”; “Saper, Silberstein et al

– establishment of ICD-9 code for MM”; ‘Fishbain et al – *Pain Medicine* supplement on oxymorphone”; ‘Portenoy/Pasternak/Jackson – Opioid rotation roundtable & upcoming publication in “*J Pain Symptom Manage*”; and “Fishman & Dahl – national FSMB/state pain initiative project.” ENDO-CHI_LIT-00237750.

Documentation requesting that the doctor be designated as a KOL had to be submitted for review by marketing and medical affairs for approval. ENDO-CHI_LIT-00515301. Exceptions to the Fair Market Value payment restrictions were commonly requested for doctors identified as KOLs. ENDO-CHI_LIT-00217550. These exceptions allowed Endo to pay the KOL in excess of the uniform fee established for other non-KOL healthcare providers.

On May 8, 2012, pursuant to an investigation into the relationship between opioid manufacturers and non-profit health care organizations, the Senate Finance Committee asked Endo to disclose the amount of funding it had paid to prominent KOLs who advocated for the use of opioids, including Russell K. Portenoy, M.D., Scott M. Fishman, M.D., Perry G. Fine, M.D., Lynne R. Webster, M.D., Rollin M. Gallagher, M.D., Bill McCarber, M.D., Martin Grabois, M.D., and Myra Christopher, M.D. ENDO-OR-CID-00806002. In Endo’s July 6, 2012 response, it disclosed the following total payments: \$73,855.10 to Dr. Portenoy from 1999-2002 for Pain Education, Honorarium and expense reimbursement from 1999-2002; \$8,000 to Dr. Fishman from 2002-2004 for Pain Education; \$36,881.20 to Dr. Fine for pain education, outside contracting services, project consultant from 2002-2007; \$22,500 to Dr. Gallagher for pain education and project consulting from 2001-2005; \$45,193.30 to Dr. McCarberg for pain education, honorarium, expense reimbursement and sales support from 2001-2006; and \$4,000 to Dr. Grabois for pain education in 2004 and 2006. ENDO-OR-CID-00754369. Importantly, Endo reported that the disclosures were for direct payments by Endo and noted the following limitation of its funding disclosure: “Indirect payments to physicians, through third party vendors for events such as

conferences, speaker programs, or seminars, may not be identifiable in the SAP system. Accordingly, payments to the individuals listed in request 1(b) by third-party vendors engaged for services by Endo may not be reported, as Endo lacks the systems infrastructure to readily track and report payments made to the individuals through third party vendors.” *Id.*

While direct payments may not have been substantial, Endo regularly employed third parties to facilitate the recruitment and payment of KOLs for various promotional and education programs. For instance, in association with a May 2011 NIPC Dinner Dialogue engagement, the APF forwarded a Faculty Responsibilities Agreement to Dr. Perry Fine in the amount of \$3,000, for his speaking services at the dinner. CHI_001212779. Notably, this payment was not included in the fee disclosure made by Endo to the Senate Finance Committee, as it was within the “indirect” payment category expressly disclaimed by Endo. ENDO-OR-CID-00754369.

Notable KOLs Endo collaborated with include, but are not limited to: Russell Portenoy, MD; Ray Sinatra, MD; Betty Ferrell, MD; Gilbert Fanciullo, MD; Bruce Nicholson, MD; Charles Argoff, MD; Martin Angst, MD; Paul Christo, MD; Lynn Webster, MD; Richard Rauck, MD; Alan Matsumoto, Md. ENDO-CHI_LIT-00547230. In the Midwest Region, notable KOLs included Dr. Schertzinger (West Chester, OH), Dr. Otten (Columbus, OH), Dr. McGowan, Dr. Hailey, Dr. Peppler, Dr. Scheperle, Dr. Mann (Columbus, OH), and Dr. Sueholtz. ENDO-OPIOID_MDL-00627336. In 2013, one presentation boasted “Strong relationships with 1,000 Therapeutic Experts (KOLS).” ENDO-OPIOID_MDL-00665227.

On February 15, 2013, Endo submitted a labeling supplement proposing additions to the label including “pre-and postmarketing data from in vitro and in vivo abuse potential studies to the DRUG ABUSE AND DEPENDENCE section of the Package Insert.” ENDO-OR-CID-01174358. On May 10, 2013, the FDA denied the application and highlighted the following concerns about the formulation:

no pharmacokinetic studies measuring serum concentrations following nasal administration or assessing the ability to insufflate have been conducted. Additionally, no human abuse liability studies examining abuse by the nasal route of administration have been conducted. The ease with which the product can be manipulated, and the ease with which oxymorphone can be extracted from the manipulated product, are not consistent with a formulation that would provide a reduction in oral, intranasal or intravenous abuse of Opana ER.

Id.

The FDA also cited concerns with the post marketing data Endo submitted in support of the label change. The FDA found

[t]he postmarketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse of Opana ER due to:

- the short period of time represented
- the overlap of prescriptions for both the original formulation of OPANA ER and reformulated OPANA ER during the first quarter of the reporting period
- the continued availability of original OPANA ER throughout the reporting period
- the possible misclassification of the original and reformulated products based on the similar appearance of the two products.

ENDO-OR-CID-01174359.

As part of the post-launch plan for Opana ER, Endo introduced a Promotional Speakers Program to support the new product. The objective of the program was to “educate physicians on the benefits and proper use of Oxymorphone” and to “encourage trial of Oxymorphone with prescribers of long acting opioids.” ENDO-CHI_LIT-00551008. The plan was to hold a “series of promotional meetings with high prescribers of strong opioids.” *Id.* According to a market update report from October 2006, 15 health care providers were trained as speakers and 65 additional health care providers signed up for programs slated to run from October 27-29, 2006. ENDO-CHI_LIT-00547005.

With respect to Mallinckrodt, Plaintiff states as follows:

Mallinckrodt maintained a detailed “target” list of KOLs with respect to specific products or treatment areas. Mallinckrodt has not, however, produced a comprehensive list. For example, MNK-T1_0002370786 lists the Addiction Treatment KOLs as of May 2014. Other documents contain KOLs for Exalgo (*see, e.g.*, MNK-T1_0000858528 (2009) and MNK-T1_0002287371 (2010)). MNK-T1_0006314623 contains MSL recommendations for publications and ISR advisory boards for Exalgo as of February 2010. In terms of the events at which individual KOLs spoke, Mallinckrodt is in possession of this information but has not provided it.

The amounts paid to each KOL is information that is solely in Mallinckrodt’s possession, and to date Mallinckrodt has been unable or unwilling to provide this information in a usable form. Mallinckrodt has produced over two thousand pages of individual grant documents. *See* MNK-T1_007765741 – MNK-T1_7775776. In addition, Mallinckrodt has produced a “payment report” from its J.D. Edwards database. *See* MNK-T1_008005740. This payment report consists of over 199,000 line entries, and appears to encompass every third party that Mallinckrodt did business. For many entries there is no description of the service being provided. Another document, MNK-T1_0001499354, lists 2010 and 2010 budgets for speakers’ bureaus but does not provide any break-down of payments. Neither Mallinckrodt’s 30(b)(6) designee on the topic of KOL and front group payments, nor Mallinckrodt’s senior finance director, could provide an aggregate break-down of payments. *See* 30(b)(6) Deposition of Kevin Webb and Deposition of Jeff Kilper.

With respect to Purdue, Plaintiff states as follows:

Dr. Portenoy and Dr. J. David Haddox of Purdue were both part of the group that drafted the 1995 APS-AAPM Consensus Statement on Quality Improvement Guidelines for the Treatment of Acute and Cancer Pain. PDD1501803068 at -74. Also among that group was David Joranson of the University of Wisconsin’s Pain & Policy Studies Group (“PPSG”), along with Dr.

Daniel Carr and Dr. Richard Payne, who would both become prominent KOLs (especially tied to Janssen). PDD1501803068.

Portenoy had a relationship with Purdue as early as August 1997, as shown by a letter requesting a \$100,000 grant for initiatives at Beth Israel Medical Center ("Beth Israel"). PKY180772092. Portenoy mentions that other "industry leaders" have responded positively to his request. Beth Israel received millions in industry funding over the years. ENDO-OPIOID_MDL-01610298.

Dr. Haddox and Dr. Portenoy had a close, collegial relationship, emailing each other directly about meetings, papers, grants, and various work matters. PPLPC020000005715 (Portenoy requests names of doctors who can speak to negatives of opioid use, Haddox responds); PKY180650211 (Haddox requests Portenoy give presentation covering treatment of non-cancer pain); PKY180650171 (Haddox requests Portenoy presentation differentiate addiction terminology); PDD8801291781 (Portenoy discusses opiophobia for Purdue); PPLPC025000013093 (Haddox requests dinner meeting at conference); PPLPC025000014468 (Haddox invites Portenoy to participate in educational task force); PKY182717470 (Haddox thanks Portenoy for commentary on panel).

Haddox was connected to the then-new ABPM certification and strongly encouraged Portenoy to take and promote the examination. PPLPC025000005590. The goal was to "certify that physicians possess requisite knowledge to practice safe, effective, and ethical pain medicine." PPLPC025000005590.

Portenoy ultimately agreed to take the ABPM certification, telling Haddox that Purdue "changed the world" in cancer pain management and should do it again with respect to "these areas" that they recently discussed. PPLPC025000005606 (the treatment of chronic, non-cancer pain). Documents from both Janssen and Purdue demonstrate they viewed chronic, non-cancer

pain as an opportunity to expand sales. Haddox wrote Portenoy's required letter of recommendation for the ABPM certification. PPLPC0250000014968; PPLPC0250000015981.

Portenoy also requested a grant for Beth Israel pain management initiatives. PPLPC025000005606. Beth Israel's Development Director also emailed Haddox, calling Haddox and Portenoy "crusader[s] with a cause" and attaching a proposal for the Project on Pain and Chemical Dependency, focusing on the "true risk of addiction" when using opioids in treatment of chronic, non-cancer pain (among related topics). PPLPC025000005743-44. Haddox emailed Portenoy several times, assuring him that he is looking into the grant funding, sometimes inquiring what other companies are offering. PPLPC025000005725, PPLPC025000005759, PPLPC025000006722, PPLPC025000007427.

Haddox also helped Portenoy put together a listserv for Beth Israel's Project on Pain and Chemical Dependency. PPLPC025000005739-41. The initial email included various doctors, government insiders, and PPSG member Joranson. PPLPC025000005739. Portenoy emails the listserv at one point, lamenting that "use of opioids relies so strongly on personal impressions" because of lack of research. PPLPC009000009824.

Dr. Passik joins Portenoy in requesting money from Purdue in February 2001, stating that they need \$1.5 million from industry partners to fund the Project on Pain and Chemical Dependency. PPLPC025000019244. In the same email, Passik notes that he wrote a letter to a journal discussing diversion and stating that OxyContin was not the real problem; he also mentioned giving a talk for Janssen in which he defended OxyContin. *Id.*

In April 2001, Portenoy sent a letter to Goldenheim at Purdue, recommending an "unusual" partnership between industry competitors, along with academic medicine. PKY180702082. Portenoy input from regulatory agencies and law enforcement, and he requests a grant of \$300-\$500k annually. *Id.*

After April 2001, after Portenoy sent the Goldenheim letter and the documents on which Portenoy appears center more around various advocacy groups and around Janssen.

Around August 2001, Portenoy became co-chair of The National Pain Education Council ("NPEC"), which Janssen spent millions to create to handle its unbranded marketing, including doctor training programs and other initiatives. Richard Payne was his co-chair (with ties to the Robert Wood Johnson Foundation), and the group included a member of JCAHO and a member of PPSG, among others. JAN-MS-00306713. According to January 2003 meeting notes, Drs. Payne and Portenoy would be paid "\$15M" individually and "\$25M" to their respective institutions in honorarium. JAN-MS-00312977. In late 2002, Purdue was approached about NPEC funding. PPLPC01900029262; PPLPC01900029246.

One of NPEC's main goals was to position long-acting opioids as preferred therapy for the treatment of chronic pain. JAN-MS-00787624. By November 2003, NPEC's website was receiving more than 5,000 views a day some days, 57% of visitors were doctors, half were repeat visitors, and 29% returned more than six times. JAN-MS-00315204.

Portenoy met with the DEA in his NPEC capacity. JAN-MS-00777576. By February 2002, Portenoy advises Janssen's consultants, Discovery International, that NPEC should not seek DEA endorsement; rather, they should seek it from Joranson's group, which would encompass the DEA and FDA. JAN-MS-00312347. Meetings between NPEC and DEA took place at APS. *Id.* NPEC also engaged the Government Accounting Office about Medicaid reimbursement. JAN-MS-00315240

The NPEC meetings appear to converge with meetings of members of the "Pain Forum" and the "RX Action Alliance." These meetings continued at least through March 2004, with members of PPSG, APF, RWJF/Last Acts, and the DEA. CHI_001703128; CHI_001703770.

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Portenoy edited a publication by DOJ, RWJF, and PPSG regarding diversion. WIS_PPSG_000668; WIS_PPSG_000870.

APF sponsored a “corporate roundtable” with Purdue, Janssen, Endo, and other corporations, which Portenoy attended. CHI_000185456.

During this time, Portenoy continued to advise both Purdue and Janssen on various matters. PKY181288804 (requesting funding for documentary and online symposium); MDL_ASPE_000000225 (randomized controlled trial of oxycodone sponsored by Purdue and conducted by Beth Israel); E513_00002943 (consulting on a drug study); PPLPC028000089676 (advising Purdue of contact to consult on buprenorphine); JAN-MS-00725920 (advising Janssen on AP-48 product). He also had interaction with Endo and Teva. ENDO-OPIOID_MDL-01766731(Portenoy and Fine agree to assist with opioid handbook); TEVA_MDL_A_08240715 (Portenoy answers questions on Actique study).

Portenoy’s resume demonstrates his positions in various front groups and their committees (including APF, APS, AAPM, Last Acts/RWJF), awards he received from industry, and publications (showing evolution from cancer to non-cancer pain treatment). RP_0202712.

Transcripts of Portenoy’s testimony before governmental entities provide further evidence of the RP_021306 (Prescription Drug Abuse Hearing before AG Blumenthal); RP_021194 (OxyContin: Balancing Risks and Benefits Hearing before US Senate).

PAIN IS “UNDERTREATED”

An article written by the APF demonstrates that surveys suggesting that pain is “undertreated” were produced by the pharmaceutical companies – and for the purpose of gaining media placement and influencing consumer attitudes. JAN-MS-02325533.



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**Review of American Pain Surveys
Designed to Gain Media Placement and/or
Influence Consumer Attitudes**

1994-Present
Prepared by the American Pain Foundation
May 2002

Summary

The following is a review of nine US pain surveys, arranged by date, that were conducted over the last seven years. All but one—*Pain in America: A Survey of American Attitudes Toward Pain*, sponsored by the Mayday Fund—were commissioned by pharmaceutical companies and developed by public relations agencies for the purpose of influencing consumer attitudes and promoting a particular product or a class of drugs. Several of these surveys were done in collaboration with nonprofit organizations. Some of the surveys had a particular focus (e.g., effect of pain on the elderly, pain and work, pain and gender differences, etc.).

The APF researched the all the surveys conducted by the industry and determined them to be biased. JAN-MS-02325533 at -34.

To date, all but one (the Mayday survey) of the general, non-disease specific, national pain surveys were commissioned by individual pharmaceutical companies for the purpose of creating awareness about pain and (indirectly) promoting a product or class of drugs. The most commonly used method to accomplish this was to craft questions designed to demonstrate the dangers, or lack of effectiveness, of other types of drugs or delivery systems. . . . None of the surveys were initiated by nonprofit pain advocacy or professional organizations or epidemiological research organizations. Nonprofit organizations were often involved to lend credibility to the studies and increase likelihood of media coverage. Reputable polling firms (Louis Harris, Roper Starch, etc.) were employed to conduct surveys to give credibility to them.

JAN-MS-02325533. The APF report concludes that there is a need for a large-scale, unbiased pain survey, conducted by epidemiologists. JAN-MS-02325533 at -35. "Everyone working to improve pain management . . . needs reliable and current statistical data to inform and guide their work. As

the old adage goes, *you cannot manage what you cannot measure.*" JAN-MS-02325533.

The studies that APF researched include the following:

1. 1995 *National Pain Survey* by McNeil Pharmaceutical: "The key finding was that the majority of patients were reluctant to take certain types of drugs because of fears about side effects such as gastrointestinal bleeding and potential for addiction." *Id.* at -36. The survey coincided with the 1995 FDA approval and launch of Ultram (a version of which is co-promoted by Purdue).
2. 1996 *Pain and Absenteeism in the Workplace* by Ortho McNeil Pharmaceutical: "The study was designed to promote Ultram . . ." Its key finding was that untreated pain was a detriment to business. *Id.* at -36.
3. 1997 *Pain and the Older Americans Survey* by Ortho McNeil Pharmaceutical: Key finding was that a large number of older Americans take too many NSAIDS and end up with gastrointestinal problems. The study targeted potential users of Ultram. *Id.* at -37.
4. *The 1999 National Pain Survey* by Ortho McNeil Pharmaceutical: The survey is a follow-up on the 1994 survey that examined "the analgesic dilemma," not included in this APF report, which looked at patient fears about side-effects, addiction, and prescribing practices. *Id.* at -40. Among key findings: 9 in 10 physicians were concerned about opioid side effects, including addiction. *Id.* An email within Janssen on October 29, 1999 regarding KOL interviews is potentially related.
5. 2000 *Pain in America: A Research Report* by Merck & Company: Among the key findings, nine in ten Americans suffer from regular pain. *Id.* at -41.
6. 2000 *Chronic Pain in America: Roadblocks to Relief* by Janssen Pharmaceutica, the American Pain Society, and the American Academy of Pain Medicine: This survey was conducted between November 1998 and January 1999. Its stated purpose was to heighten awareness among consumers and the medical community on the issue of chronic pain and the need to treat it aggressively. *Id.* at -43.
7. 2000 *A Survey of Pain in America* by Purdue Pharma (Partners Against Pain): The survey was designed specifically to promote OxyContin. *Id.* at -45.
8. 2001 *Gender Attitudes Toward Chronic Pain* by Purdue Pharma (Partners Against Pain) and the National Women's Health Resource Association. *Id.* at -46.
9. 2002 *Pain in Maryland* by Medtronic, Abbott, the American Pain Foundation and the Maryland Pain Initiative. *Id.* at -47.

Purdue internally recognized that later surveys by Janssen were "clever marketing."

PLPC009000079874.

Shortly before the above report was published, the executive director of the APF and Dr. Richard Sackler of Purdue had a direct relationship. On February 11, 1999, the executive director of the APF, Jim Guest, emailed Dr. Richard Sackler, thanking him for a \$250,000 contribution and alerting him to impending legislation. PPLPC026000000291. Guest and Sackler discussed that Guest approach Janssen to leverage a similar grant. *Id.* Guest followed up on it, because the APF approached Janssen asking for \$250,000. JAN-MS-01052077. *See also* PPLCP018000004292 (email with evidence of funding from Ortho-Biotech, APS, Knoll, and Endo).

By August 5, 2000 Purdue expected return on that financial support for APF. Robin Hogen emailed Haddox about APF executive director Jim Guest, saying “[i]f they want our bucks (and they honestly cannot survive without industry support) they are going to have to learn to live with ‘industry’ reps on their board. I don’t think they can expect huge grants without some say in governance.” PPLPC025000012558. Guest discusses with Sackler that the APF does not want industry connections on the board because it wants to avoid the appearance of impropriety – while keeping Sackler informed about the APF’s every move.

Guest’s email also referenced the Pain Relief Promotion Act, stating that the Pain Care Coalition (APS, AAPM, ASA) specifically asked for the declaration that this is the “Decade of Pain Control and Research.” PPLPC025000012558. June Dahl of the Pain & Policy Studies Group was also involved. PPLPC025000012558.

Pre-2001 Guidelines

Prior to 1994, physicians treated cancer pain according to the World Health Organization’s (“WHO”) three-step analgesic ladder. *See* PKY183222319 at -22. Step 1 of the WHO ladder represented treatment of mild pain with aspirin, acetaminophen, and NSAIDS. PKY183222319. Step 2 of the WHO ladder represented moderate pain, treated with “weak” opioids like codeine,

oxycodone, and hydrocodone. PKY183222319. Step 3 represented severe pain, usually treated by either fentanyl or morphine. PKY183222319.

In 1994, the Agency for Health Care Policy and Research ("AHCPR") adopted Clinical Practice Guidelines for the Treatment of Cancer Pain. The AHCPR is a branch of the Department of Health and Human Services ("HHS").

Purdue recognized that guidelines could be used to sell MS Contin and partnered with AHCPR to distribute the guidelines. PDD1706039146. Indeed, Purdue timed the launch of its Partners Against Pain program to coincide with the release of the AHCPR guidelines. PKY180628795.

March 7, 1994

F-D-C REPORTS — "The Pink Sheet"

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PURDUE FREDERICK "PARTNERS AGAINST PAIN" PROGRAM LAUNCHED TO COINCIDE WITH AHCPR GUIDELINES; PURDUE FREDERICK SALES FORCE WILL DISTRIBUTE GOVERNMENT GUIDES

Purdue Frederick is incorporating clinical practice guidelines from the Agency for Health Care Policy & Research into a promotional/patient education campaign for pain control.

PKY180628795. In a Quarterly Report about MS Contin from Michael Friedman to the Sacklers, Mr. Friedman recorded:

These guidelines are a selling tool that we can use. . . . In anticipation of the publication of the AHCPR guidelines we trained influential physicians on how to deal with media and enlisted their support for our public relations campaign. Two days before the guidelines were published our press-kit was sent to approximately 600 reporters and our video news release and sound tape was sent to over 150 TV and radio stations . . . We have numerous reports of our product being displayed in a favorable light during press coverage of the AHCPR guidelines.

Id. PDD1706039146 at -47.

The Pink Sheets, a daily business publication, reported that "[t]he Purdue Frederick adoption of the AHCPR guidelines into its program is one of the most direct uses of a recommendation from that agency by a pharmaceutical maker." PKY180628795. The University

of Wisconsin, home to the soon-to-be-formed Pain & Policy Studies Group, was also involved in creation of the guidelines. As part of the AHCPR guideline distribution, one of AHCPR's cancer pain board members, Charles Cleeland, PhD, of the University of Wisconsin Medical School, authored an article about the undertreatment of cancer pain, published in The New England Journal of Medicine. PKY180628795. Also involved in the Purdue program launch were two cancer specialists from the Fox Chase Cancer Center in Pennsylvania, both of whom were consultants to the AHCPR in creating the guidelines: Michael Levy, Md/PhD, and Pamela Kedziera, RN. PKY180628795.

Purdue recognized that the AHCPR guidelines were favorable to OxyContin in that they 1) "reinforce [the] principle of tailoring pain medications to the individual patient by titrating upward before switching, 2) "using adjuvant agents," and 3) "treating specific types of pain with individual agents," as opposed to mixing, for example, opioids and NSAIDS. PKY180287212 at -20. "The dosing flexibility offered by OxyContin is consistent with these guidelines as a Step 3 agent." PKY180287212

Purdue's intent, however, was to position OxyContin in Step 2 of the WHO ladder, for more moderate, non-cancer pain, and to push fentanyl to the most extreme of Step 3. *Id.* at -22, 25-29. Purdue intended to do this by "engineering" successful trials. *Id.* Purdue also planned a play, direct mailers, and certification programs for oncology nurses (through a grant to ASPMN), and a media roundtable (using representatives of relevant associations for "third-party credibility"), and press information packages. PKY180287212.

By 1995, Purdue was watching the APS guideline process. PDD1501803068. An unidentified Purdue custodian printed and highlighted a copy of the 1995 APS Consensus Statement, "Quality Improvement Guidelines for the Improvement of Acute Pain and Cancer Pain." PDD1501803068. The highlighted portions read:

By making the magnitude of the problem [of undertreated pain] apparent and committing the institution to change, pain treatment QI programs can provide a foundation for a multifaceted approach that includes education of clinicians and patients, design of informational tools to minimize errors in prescribing, and improve coordination of the process of assessing and treating pain. . . . The targeted outcome was that each patient would receive timely and optimal doses of analgesic drugs.

PDD1501803068 at -68-70. The article also notes that the draft guidelines were circulated to the full membership for comment. PDD1501803068 at -70. The drafting committee was composed of the following members: Mitchell B. Max, MD (National Institute of Health/National Institute of Dental Research); Marilee Donovan, Ph.D., RN (Kaiser Sunnyside Medical Center); Christine A. Miaskowski, PhD, RN (University of California); Sandra E. Ward, PhD, RN (University of Wisconsin); Debra Gordon, MSN (University of Wisconsin); Marilyn Bookbinder, PhD, RN (Memorial Sloan-Kettering Cancer Center); Charles S. Cleeland, PhD (University of Wisconsin); Nessa Coyle, RN, MS (Memorial Sloan-Kettering Cancer Center); Margaret Kiss, MS, RN (Memorial Sloan-Kettering); Nora Janjan, MD (University of Texas M.D. Anderson Cancer Center); W. Thomas Edwards, PhD, MD (Harborview Medical Center). Contributions from the following people were also noted: Margo McCaffery, RN, MS; Carol Howe, MSN; Susan Hagan, BSN, MS; Mary Layman Goldstein, RN, MS; Susan Derby, RN, MS; Mary Born, RN, MS; Betty Ferrell, PhD, RN; Jan Frandsen, RN, MS; Daniel B. Carr, MD; Sri Vasudevan, MD; Russell Portenoy, MD. PDD1501803068 at -74.

By May of 1998, the American Geriatric Society published new guidelines for treating pain in the elderly, in which Janssen was involved. JAN-MS-00270843. An email was sent around Janssen, specifically the Ortho-McNeil division (then responsible for Ultram), inquiring as to whether the company had any influence over the AGS guidelines. JAN-MS-00270843. The answer was that Ortho-McNeil did not but that “[i]t was all driven by the Tylenol brand.” JAN-MS-00270843. “[W]e were invited to join the MCP folks at a final meeting at AGS . . . I’d inquired

as to whether we could somehow get ULTRAM also considered for inclusion in these g'lines, and unfortunately was told that their scientific advisors had already signed off on them (the ULTRAM brand was aware of this)." JAN-MS-00270843. Because of coverage on NSAIDS and undertreatment of pain, the Ortho-McNeil strategy going forward was get media to discuss effective treatments for chronic pain (which would presumably include ULTRAM and other opioids). JAN-MS-00270843.

Purdue and Ortho McNeil were at the time meeting to discuss Ultram. PPLPC018000002278. Friedman's notes from an April 1997 meeting reveal that Ortho McNeil sought to position Ultram as an alternative to "dangerous" NSAIDS. The two sides discuss broader pain policy, but primarily with respect to scheduling and the FDA, not guidelines.

From August 23-25, 1998, Purdue was looking at pain guidelines. See the PPSG website of various state guidelines and articles. PKY183028750, PKY183028698, PKY183052486.

The 2001 JCAHO Guidelines & Model State Guidelines

The WHO, AHCPR, and APS guidelines "had not worked," meaning they were not being uniformly implemented by healthcare providers. David Baker, MD, MPH, *The Joint Commission's Pain Standards: Origins & Evolution*, The Joint Commission (May 5, 2017), https://www.jointcommission.org/assets/1/6/Pain_Std_History_Web_Version_05122017.pdf. Under those guidelines: "Physicians were 'rarely held accountable' for inadequate pain control, and they had not implemented systems to address the problem." *Id.*

Purdue representatives sought creative ways to enforce older guidelines. They quizzed doctors on the AHCPR guidelines, "establishing the federal guidelines as the *Standards of Care* for cancer pain management" and making doctors members of "The Pain Team." PKY180242433. Purdue representatives would then "transform the 'Big Picture' to a personal level" by "showing

the Federal Guidelines information is being incorporated into the survey evaluation process for JCAHO (Joint Commission on the Accreditation of Healthcare organizations).” The implication of the “personal,” is that the doctor could get in trouble for undertreating pain. “Talking about their personal role in patients care and the practical application of the Federal Guidelines recommendations usually leads to a discussion of a patient they currently have under their care. At this point the Purdue Frederick sales representative is transformed into a Pain Management Consultant.” *Id.*

On November 12, 1999, Janssen sent a bulletin out to its sales force about a report in the *British Medical Journal* of a doctor being disciplined for undertreating pain. JAN-MS-02728546. “One of the issues that is driving the rapid expansion of the pain market is the changing attitude towards the treatment of chronic, severe pain.” JAN-MS-02728546.

The Robert Wood Johnson Foundation (“RWJF”) funded the Joint Commission to develop pain standards in collaboration with the University of Wisconsin-Madison School of Medicine (Pain & Policy Studies Group) “and experts from around the country.” JAN-MS-02728546. Those standards would go into effect in 2001. The Robert Wood Johnson Foundation also funded creation and dissemination of the Model State Guidelines through the Federation of State Medical Boards. PDD1706042217. It also funded the Pain & Policy Studies Group. PDD180550457. Dr. Payne’s resume shows substantial overlap between RWJF and Janssen advisory boards. JAN-MS-00402671.

The RWJF currently owns nearly \$2 billion in J&J common stock, and the organization has been funded from its inception (at least in part) from that stock grant.²

² <https://www.rwjf.org/content/dam/files/rwjf-web-files/Financials/FY2017-RobertWoodJohnsonFdn-FS.pdf>

Around July 1997, an unidentified Purdue employee wrote an internal memo regarding the need for consensus guidelines on the treatment of non-malignant pain. PKY181320029; PKY183033731. The memo references a Janssen study in Business and Health as demonstrating undertreatment of pain and suggests creating the guidelines to distribute to Purdue's "core audience involved in non-malignant pain management." PKY183033731.

By 1998, Purdue had thought leaders teaching CMEs on "Defining New Standards of Care" through the University of Wisconsin Medical School (Pain & Policy Studies Group), which was currently working on the JCAHO standards. PKY180947825. At least one of the thought leaders, Cohen, disclosed that he received funding from both Janssen and Purdue. PKY180947825.

By late August of 1998, Purdue drafted out its plan to influence pain treatment guidelines disseminated by state medical boards – and recorded that plan in a memo. See PKY183033795. An early version of the memo records that "some physicians have stated that not relieving pain optimally is tantamount to moral and legal malpractice." PKY183028056 at -56. The memo focuses on barriers to using opioids in non-cancer pain, identifying those barriers as 1) burdensome state laws and regulations, 2) inadequate training of providers, 3) provider concerns of addiction and investigation, 4) societal attitudes, and poor coordination among policy makers, consumer groups, purchasers, and health care providers. PKY183028056 at -56-57. "Toward this end, the Federation of State Medical Boards has drafted model guidelines for prescribers, which the federation hopes will be adopted universally. Pain policy analysts we spoke with argue that a non-legislative approach to affecting change (*i.e.*, adopting practice guidelines) is better than a legislative approach because guidelines are easily modified as the practice of pain management changes." PKY183028056 at -58.

The early version of the memo discusses "opportunities" and cites "independent research organizations" who study pain and policy: the Midwest Bioethics Institute and the Pain & Policy

Studies Group. *Id.* The memo states that the groups' large research projects have been funded largely through the Robert Wood Johnson Foundation; it gives one example of an \$11.25M program, Community-State Partnerships to Improve End-of-Life Care, though which grant applicants are advised to include in their proposals plans to "develop and disseminate guidelines that promote effective pain management." *Id.* 47 of 50 states submitted programs. PKY183033795 at -98.

The Purdue guidelines memo eventually became a formal Partners Against Pain booklet titled "Fostering Change in the Pain Management Environment," Purdue worked on the project through Fleishman-Hillard, Inc., a public relations firm. PKY183028056. Program objectives: "Strategically foster public policy changes in the use of opioids for pain management. Impact the prescribing environment in which opioids are used for responsible pain management. Position Purdue Pharma with key stakeholders in a manner that will be helpful to future product launches." PKY183033795 at -99. The memo determines that the most impact can be had on the state level, and it identifies specific states to start with. *Id.* at -03.

"This plan will support existing state efforts, such as The Robert Wood Johnson Foundation's Community-State Partnership Program, which will put tremendous dollars and influence behind reworking pain management guidelines and legislation. Our preliminary assessment is that this program presents opportunities for alliance building for Purdue Pharma." *Id.* Purdue then produced the brochure titled "The Seven Myths of Pain Management" that it disseminated as an educational piece for "decision-makers, opinion shapers and consumers." *Id.* at 00.

Purdue and Janssen had tactical meeting around October 13, 1998, bringing leadership and sales representatives together to discuss Ultram SR business plans. JAN-MS-00270848. Purdue and Janssen met again in November 10, 1998 to discuss abuse liability for Ultram SR in relation

to their NDA submission to the FDA. JAN-MS-01051749. The companies continued working together at least through January of 1999 to address clinical trial issues. JAN-MS-01051770.

Around the same time, a PowerPoint presented by the R.W. Johnson Pharmaceutical Research Institute, J&J's umbrella research subsidiary advocates for the development of pain treatment guidelines across the spectrum of painful conditions, as well as pain management conference and a coordinated education program for physicians, insurers, and patient advocacy groups. JAN-MS-01003804; *see also* JAN-MS-02759375, JAN-MS-00456512, JAN-MS-02727945. Janssen believed guidelines were "underutilized." JAN-MS-02727943. It is also around this time that Janssen begins considering combining J&J's pain franchise, currently split between Janssen, Ortho-McNeil, and Pri-Cara. JAN-MS-02727943.

On December 1, 1998, Janssen met with the AGS board of directors to discuss updating the new AGS guidelines. JAN-MS-00270846.

In December 1998, Purdue was already anticipating using the JCAHO guidelines to sell – before the guidelines were published, including a JCAHO "compliance kit" on making pain management appropriate for all patients, not just the dying. PKY18122672.

By February of 1999, Purdue sought to partner with the VA and APS on the "Pain: The 5th Vital Sign" campaign. PKY183036326. Purdue planned to "[e]xtend base of support to states via VA network, state medical boards, or managed care organizations." PKY183036326. at -26. At the time, Purdue already envisioned a consensus statement from APS and AAPM as part of the plan, intending to pass out the guidelines and consensus statements at CME programs. PKY183036326. at -28. "Foster changes in pain management through educational seminars directed at physicians and thought leaders" PKY183036326. at -27.

Initially, Purdue intended to target ten states, those with the best business development opportunities. PKY183036326. at -26. This was accomplished through Fleishman-Hillard and

Lyons Lavey Nickel Swift, Inc. *Id.* On August 11, 1999, an internal email asked how to get “mileage” from a New York Times article about pain killers and new guidelines. PPLPC012000005648. The response was that Purdue should put together programs based on its experience in California, Nevada, and Ohio. PPLPC012000005648. “If we can get the governing board’s message out, it can only help us sell more.” PPLPC012000005648. By March of 2001, a Janssen consultant, Discovery International, recommends targeting the state medical boards to expand the FSMB 1998 Model Guidelines, as well as breaking down the JCAHO guidelines to make them more easily accessible to doctors. JAN-MS-003131999 at -01.

By 1999 Purdue sent an employee to speak with “key JCAHO players” about Purdue’s interests. PDD1701879922.

In June 2000, evidence links Purdue and RWJF. PPLPC029000018652. The parties intended to meet to discuss how to partner with RWJF’s “Last Acts” campaign. PPLPC029000018652. Michael Friedman and Robert Reder attended the meeting, and potentially Haddox. PPLPC029000018652.

In September 2000 a Purdue publication titled “Preparing for JCAHO: Implications for the Case Manager” stated: “In 2001, for the first time, all JCAHO-accredited institutions and organizations will be expected to demonstrate their ability to assess and manage pain in all patients, not just in the final days of life, but across the continuum of care.” PDD8801316960. JCAHO education materials became standard for Janssen representatives by November of the same year. JAN-MS-02327808.

Then, in November of 2000, several companies cooperated with the NPC and JCAHO to disseminate the new guidelines. JAN-MS-00654711; JAN-MS-00654707-11. On November 28, 2000, Jeann Gillespie from the NPC emailed employees from Janssen, Knoll, AstraZeneca, Abbott, Pfizer, BMS, Merck, and, curiously, Monsanto to inform them that the JCAHO “pain

management project” is moving forward. JAN-MS-00654711. Through the project, NPC and JCAHO intended to produce pain management monographs with a prestigious editorial advisory board; Gillespie asked for recommendations, suggestions, and comments. JAN-MS-00654711. She also promised to send out invoices and logistics for the companies’ financial commitments. JAN-MS-00654711.

On December 8, 2000, Bruce Moskowitz sent Gary Vorsanger an email about the NPC JCAHO project, attaching an update and notes from an October 19 call. JAN-MS-00654707. JAN-MS-00654709. The parties discussed educational monographs on pain treatment to “raise awareness and identify gaps.” JAN-MS-00654709. “This approach is high level and non-drug specific, which is essential for collaboration.” JAN-MS-00654709. An expert panel and monographs were proposed, with the panel to include “leaders and stakeholders that have experience in measuring and improving compliance with pain management guidelines.” JAN-MS-00654710. In the meeting, Dave Kerr from Knoll discussed sponsoring two pain-management summits with Purdue. JAN-MS-00654709. A \$50,000 investment was requested from each company. JAN-MS-00654709.

The Defendants had input on the monographs. On April 1, 2001, Moskowitz sent a draft of the Pain Management Monograph from the NPC to an employee to “determine whether any treatment guidelines that include OxyContin and Duragesic are appropriately addressed.” JAN-MS-00655132. This is not the only time that Janssen would look out for the interest of Schedule II drugs as a class, not just Duragesic, as further described below. The final manuscript is attached to JAN-MS-02336600, and Vorsanger says he thinks it will be useful for marketing. Janssen intended to give it to “customers who ask about pain management.” JAN-MS-02336678. Janssen, and all of the involved companies, received 5,000 copies of the monographs. JAN-MS-02109392.

Ohio reps were taking the “5th Vital Sign” (JCAHO guidelines) message to doctors, saying, “It cannot be ignored.” JAN-MS-00306718. Telling reps to give doctors a pain contract if they are concerned about treating with opioids, and to do speakers programs to address substance abuse.

In 2002, Purdue internally discussed Janssen’s product growth, saying that growth “require[s] unique tactics such as JACHO and similar programs.” PLPC009000079874.

In April of 2016, JCAHO would release a statement on “misconceptions” surrounding the 2001 JCAHO guidelines. https://www.jointcommission.org/joint_commission_statement_on_pain_management/. Those misconceptions include:

1. The Joint Commission endorses pain as a vital sign.
2. The Joint Commission requires pain assessment for all patients.
3. The Joint Commission requires that pain be treated until the pain score reaches zero.
4. The Joint Commission pain standards caused a sharp rise in opioid prescriptions.

The University of Wisconsin’s Pain & Policy Studies Group

The Pain and Policy Studies Group, out of the University of Wisconsin, played an important role in the 2001 JCAHO guidelines. The primary individuals associated with the group are June Dahl and David Joranson.

A Milwaukee newspaper interviewed Dahl and summarized the PPSG and market expansion story:

The analytical Dahl — who, at 84, is among the oldest active Wisconsin professors — reflects, then says candidly: “It appears that the promotion of better pain management has led to more liberalization of the prescribing of opioids, which has led to an increase in the availability of the drugs, which has led to some people abusing them, and then, when they can’t get pills, to heroin as criminals promoted it.”

http://www.gmtoday.com/news/local_stories/2014/heroin-special/09102014-uw-madison-researchers-played-role-in-increasing-opioid-use.asp. Dahl told the paper that pain policy “needed

a stick,” so “Dahl (with Robert Wood Johnson funding) began encouraging the Joint Commission, which accredits most American hospitals and doctors’ offices, to adopt new pain assessment standards.” *Id.* Once JCAHO adopted the new standards, doctors and hospitals would be accountable for undertreating pain.

The Robert Wood Johnson Foundation funded the Pain & Policy Studies Group. PDD180550457; WIS_PPSG_002971; WIS_PPSG_010253; WIS_PPSG_011735. Janssen gave it startup money. PPSG members, RWJF, and Purdue communicated closely. WIS_PPSG_000511; PPLPC029000018652. Robert Wood Johnson Foundation also funded creation and dissemination of the Model State Guidelines through the Federation of State Medical Boards. PDD1706042217. Dahl was also on Janssen’s NPEC board.

Beginning in 1997, Purdue and Janssen (through Ortho-McNeil) co-promoted Ultram SR. PPLPC018000002278; PKY181968431, JAN-MS-00456519. A letter from a Purdue employee to Michael Friedman recounts how Ortho McNeil worked with the FDA to ensure that Ultram was kept at a lower schedule level – and created what was perhaps the first industry/government addiction monitoring program. PKY181424209. The letter states that Ortho McNeil had Dr. Sydney Schnoll convene a group of addiction specialists at McNeil corporate headquarters to discuss how to persuade the FDA to consider a lower schedule. Ultimately they put in place a “program where the responsibility for monitoring potential abuse problems would be shared by both government and the manufacturing organization.” PKY181424209. “The work of Dr. Schnoll’s group ultimately contributed to the non-scheduled status of Ultram.” PKY181424209. “Even though Ultram in long term use anecdotally is known to cause dependence and in some causes addiction problems, when these troubles do occur McNeil is usually the first to know about them and is able to take appropriate action to resolve the problem.” PKY181424209. The Purdue employee says this is made possible through a database that monitors prescriptions.

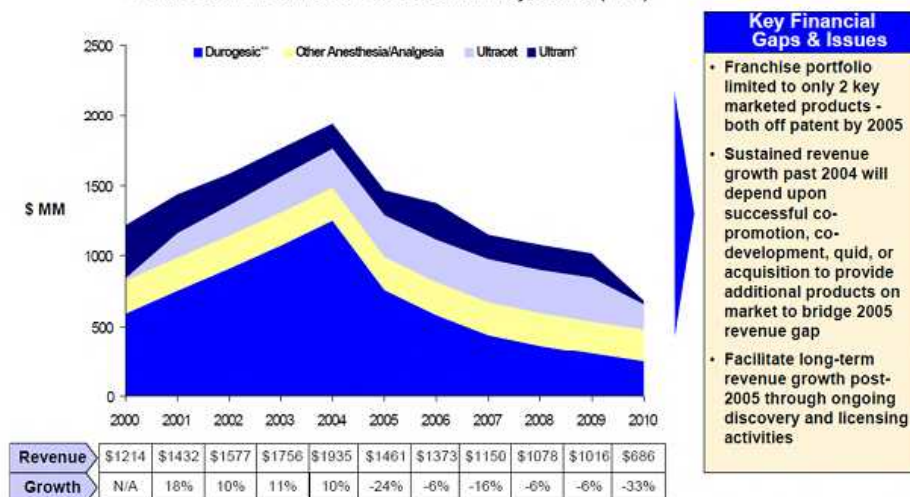
This is corroborated by Friedman's notes from the April 1997 Ultram meeting between Purdue and Ortho McNeil. PPLPC018000002278.

By May of 2000, Janssen was aware that it had a "gap problem" for the year 2005. As of that time, Janssen through Ultram and Duragesic controlled 11% of the pain and inflammation market, a share valued at \$1.3 billion to the company. JAN-MS-00456087. But without new drugs or expansion of the product base, that share drops to \$686 million by 2010, with a steep decline at 2005 before new products could be introduced. JAN-MS-00456087 at 25.

PAIN AND INFLAMMATION FRANCHISE - Internal Gap / Opportunity Analysis P - SM

Financial Projections and Growth

Franchise 10-Year Revenue & Growth Projections (WW)



Source: Portfolio forecasts. *Ultram includes Ultram & Ultram SR. **Duragesic includes Duragesic, Duragesic 12.5, & Duragesic Matrix
JJPG Confidential

Pain & Inflammation
Franchise Plan 25

Janssen knew that opioid use is increasing because of improved perception of health care policy stakeholders, specifically the WHO and NIH. JAN-MS-00456087. "Demand exists for products that offer the efficacy of opioids but do not have the associated side effects or addiction potential." JAN-MS-00456087. Janssen apparently intended to invest up to \$80M in Ultracet and

Duragesic DTC marketing, recognizing the potential in non-cancer pain and “under-treated groups.” JAN-MS-00456087. At this time, the Janssen US sales force viewed Duragesic as second detail, and there was no Janssen primary sales force for analgesia in US. JAN-MS-00456087.

Thus, Janssen began looking for a co-development project by year end 2000. “Increased industry reliance on partnerships poses both opportunities and competitive threats.” JAN-MS-00456087. The top-line recommendation: co-promote and co-develop to pursue 2005 revenue potential. JAN-MS-00456087.

At the same time, Purdue’s sales of OxyContin were just beginning to pull ahead of Janssen’s sales of Duragesic. JAN-MS-00615319. By 1997, Purdue was anticipating a generic of MS Contin, and “one of the primary objectives is to capture patients who would have been started on MS Contin to OxyContin, as quickly as possible.” PKY183222319 at -25. Janssen has been targeting the moderate to moderately-severe market for the past two to three years but making slow progress. PKY183222319. Janssen spent over \$1M in 1996, through August, advertising in Journals to target internists and PCPs (as opposed to pain specialists).

In April of 1994, Purdue commissioned Strategic and Tactical Recommendations for OxyContin’s 1996 launch; at that time, the recommendation was to position OxyContin to treat cancer pain. PKY180287212 at -13. But from the outset, Purdue intended to expand into non-cancer pain. PKY180287212 at -35. However, it appears from the Strategic and Tactical Recommendations that such an expansion would have to occur *after* the launch in cancer pain. PKY180287212 at -35. By 1998, the OxyContin budget included a plan to “enhance the acceptance of opioids for non-cancer pain.” PKY180233846 at -60. The plan was to “attach an emotional aspect to non-cancer pain so physicians treat it more seriously and aggressively.

PKY180233846. “The positive use of opioids, and OxyContin Tablets in particular, will be emphasized.” PKY180233846 at -63.

On March 20, 2000, Janssen’s Global Commercial Team (“GCT”) met to discuss objectives. JAN-MS-00478443. Among them was moving the position of Duragesic from Step 3 (“mostly cancer pain”) of the WHO pain ladder to Step 2 (“opioids-non opioids, for chronic pain overall in opioid naïve patients”) of the pain ladder. JAN-MS-00478443. The GCT expressed intent to build a “spine” for the overall commercial development, publication, and communication strategy, saying “[w]e must be the champion to insure maximal support at the OC level to grow Duragesic above the \$1 billion level before 2003.” JAN-MS-00478443. In furtherance of the scheme, Defendants convened a panel of experts in Rome to gather information for marketing Duragesic. JAN-MS-00478453. Noted was consensus that “high quality evidence to support the use of DUROGESIC in chronic non-cancer pain is required, particularly from long term studies.” JAN-MS-00478453 at 2, 4, 6. Also at JAN-MS-00478471.

Later, a February 16, 2000 email confirms a March 17, 2000, four-hour meeting between Janssen and Purdue. JAN-MS-0246903. On the agenda are Janssen’s current pain audience, Ortho-McNeil’s current pain audience, Purdue analysis, co-promotion options, and next steps. JAN-MS-0246903.

This meeting was discussed at the Janssen Global Commercial Team level because March 20, 2000 Janssen GCT meeting notes says, “VC to deliver extensive buprenorphine competitive assessment to next GCT meeting (sales forces, claims etc.) Other product mentioned: OxyContin and Palladone.” JAN-MS-00478443 at -45.

By May 2000, Janssen had created plans to present to Purdue, including a plan to co-promote OxyContin. JAN-MS-01052181. “Project Objective/Rationale: Build a partnership between Purdue Pharma LP and J&J that leverages each partner’s assets and capabilities to create

a Pan Management Franchise that is significantly larger and more profitable than that which the partners could build on their own.” JAN-MS-01052181.

A Powerful Combination

J&J

- Sales/Marketing
- Tylenol & Motrin
- Duragesic
- Ultram/Ultram SR
- Ultracet
- Intellectual property
- R&D pipeline and capabilities

Purdue

- Sales/Marketing
 - Oxycontin
 - MS Contin
 - Ultram SR
 - Palladone
 - Intellectual property
 - R&D pipeline and capabilities
-

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Business Development

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11/13/2018

Internally, the plan was called “Project Pearl.” JAN-MS-01051754. Janssen and Purdue were scheduled to meet again for a discussion about partnership alternatives on September 6, 2000. JAN-MS-01051754. Janssen internally discussed three options: Reciprocal co-promotion rights on all brands, R&D partnership for development of new brands, Joint Venture to create stand-alone pain company. JAN-MS-01051754. Janssen determined ultimately to present the reciprocal co-promotion idea, with a financial structure that revenue and profit split on all brands, J&J heavier on revenue and Purdue heavier on profit. JAN-MS-01051754. A J&J “next step” was to develop a “one Pain Sales force” configuration for J&J and the company began internally restructuring

around this time. Likewise, a June 9, 2000, PPT slide depicts Janssen's analgesic pain spectrum portfolio including OxyContin. JAN-MS-00785194.

A July 28, 2000 email from Michael Grissinger to several others at Janssen discusses the impending September meeting with Purdue to "explore ways in which we might work together in pain management." JAN-MS-01052165. Grissinger asks that the information be kept confidential. JAN-MS-01052165.

A PowerPoint envisioning mirrored sales forces, with all reps carrying both companies' products appears to be what Janssen presented at the September meeting. JAN-MS-00311050.

Potential Purdue/J&J Pain Mgt Sales Force Deploymen

- Mirror Purdue and Janssen sales force
 - Combo territory
 - Fewer JNJ reps needed
- All 5 pain products carried by all representatives
- Rotation of products would develop on 3- to 4-month cycles according to need.

	Purdue N = 700	JNJ N = 700
Primary Care	OxyContin/Palidon Ultracet/SR/DURAGESIC®	Ultracet/SR/DURAGESIC® OxyContin/Palidon
Pain Specialists	OxyContin/Palidon Ultracet/SR/DURAGESIC®	Ultracet/SR/DURAGESIC® OxyContin/Palidon
All other HVPs	OxyContin/Palidon Ultracet/SR/DURAGESIC®	Ultracet/SR/DURAGESIC® OxyContin/Palidon

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11/13/2018

On September 26, 2000, an email inside Purdue was sent in anticipation of a meeting with Ortho-McNeil surrounding co-marketing and the need for post-approval safety reporting activities.

E513_00049503. Purdue was deeply involved in creating training and education programs towards the launch of Ultram SR: “Unresolved Issues: . . . Final strategy for Ultram SR, **OxyContin and Norspan TDS** [buprenorphine hydrochloride] and its impact on Speakers training.” *Id.*

A later, November 2000 PPT shows Janssen discussing co-promotion opportunities with Knoll and, curiously, that PPT shows the imagined Janssen/Purdue sales force as part of the deal, per below. JAN-MS-00456095.

Proposed Knoll/ J&J Deployment

- Mirror Knoll and J&J sales forces
 - Combo territories
 - Sales representatives will be trained in all 5 products but carry 3
- Four sales forces of 350 representatives--2 each from Purdue and J&J
 - Allows for maximum flexibility to deliver 5 products in priority position
 - Each sales force can reach 60,000 physicians individually
 - Frequency goals attained by overlapping of physicians
 - 2.02 million primary positions with 3.23 million PDEs to allocate
- Product priorities will be developed on 3- to 4-month cycles according to need

Johnson & Johnson
Pharmaceuticals Group
Business Development

7

11/30/2018

A January 3, 2001 PPT about co-promotional opportunities mentions Purdue Frederick: “Reviewing how we can work together to help each company achieve maximum sales potential of existing and future products.” JAN-MS-00456093.



Co-Promotional Opportunities

- **PURDUE FREDERICK**
- **Reviewing how we can work together to help each company achieve maximum sales potential of existing and future products**
- **Purdue and OMP marketing teams plan to meet to discuss the options to work together.**
- **Janssen also needs to be involved in these discussions**

Janssen acted to protect *all* Schedule II drugs, including OxyContin. On April 20, 2001, Bruce Colligen at Janssen sent an email to Dennis Fitzgerald and others regarding “[t]he OxyContin issue” JAN-MS-00307337. The email worries that state legislatures are responding and suggests drafting legislative language that Janssen’s lobbyists can use “to protect J&J business interest.” JAN-MS-00307337. “We want to be certain that Janssen (Duragesic) does not get caught in the OxyContin web, but we also need to have enough foresight to look towards the future of pain management and not be too limiting.” JAN-MS-00307337. “It is not our policy to advance language that would attack a competitor’s product.” JAN-MS-00307337. The email also acknowledges that the company has fought the issue of triplicate prescription pads and has been successful over the years. JAN-MS-00307337. Abuse issues “make our job more difficult.”

Id. An April 22, 2001 S.W.O.T. Analysis says that the abuse discussion can damage the total market. JAN-MS-00478511

Purdue sent a letter to its entire sales force on April 2, 2000, telling its representatives not to sell OxyContin by talking to doctors about the potential for Duragesic abuse. PKY182107687. “Janssen Pharmaceuticals and Purdue have agreed that should either company have representatives who promote product out of label or out of policy, the name of the representative will be provided to the other company for investigation and disciplinary action if necessary.” PKY182107687. Indeed, Friedman and Norton/Gorsky spoke and wrote directly about the issue. PKY181022850; PPLPC009000036199; PKY181103719.

On August 14, 2001, Dennis Fitzgerald, Jim Eckhard, Steve Huber, David Duvall, and Ed Rady and others at Janssen met regarding OxyContin abuse issues to be discussed in front of the FDA advisory board. JAN-MS-00899138. In particular, the group was concerned about whether to get involved in the public debate. “On the plus side, [getting involved] allows us to take a position, not rely on PF [Purdue], and to acknowledge that we are already ‘involved’ by virtue of the product we market.” JAN-MS-00786155. “On the negative side, we will not be involved, we risk getting ‘linked’ with Oxycontin, and we will need to support our position.” JAN-MS-00786155. Purdue decided to take an active role and intended to reach out to John Coleman at the DEA to ask him to submit DAWN database analysis in writing. They say they should either “protect the class [which would include Oxy] from restrictive actions,” actively differentiate Duragesic as less abuse potential, or simply “leaving out our opinions (good and bad) on the use of the class”

The notes later get edited, and the editor suggests, “Advocate for aggressive treatment of pain, defend the class and ‘mention’ that there are multiple types and formulations of opioids, which have different safety/benefit profiles –including . . . Duragesic The key is not to turn

this into a promotional platform (especially since I don't think we have enough data to back up our 'less-abuse-prone' claim." JAN-MS-00899138.

Gary Vorsanger of Janssen would make a three-minute presentation to the FDA. Discovery International, a consulting group, helped to draft the message. "It was suggested that KOLs have a limited awareness as to the scope of the problem; therefore it would be advantageous to prepare a document that follows the story (in the press) over time." JAN-MS-00899138. Janssen internally admitted that its "experts" are not informed on abuse issues.

The next day, a Duragesic Tactical Plan seeks to create the NPEC, to expand further into the non-malignant pain market, to position Duragesic as the first opioid of choice, to "generate" a call to action among patients. JAN-MS-00306713. "Deliver a strong value story for long acting opioids in general and Duragesic specifically." JAN-MS-00306713. This evidences intent to grow the market for OxyContin – after the potential for abuse is understood.

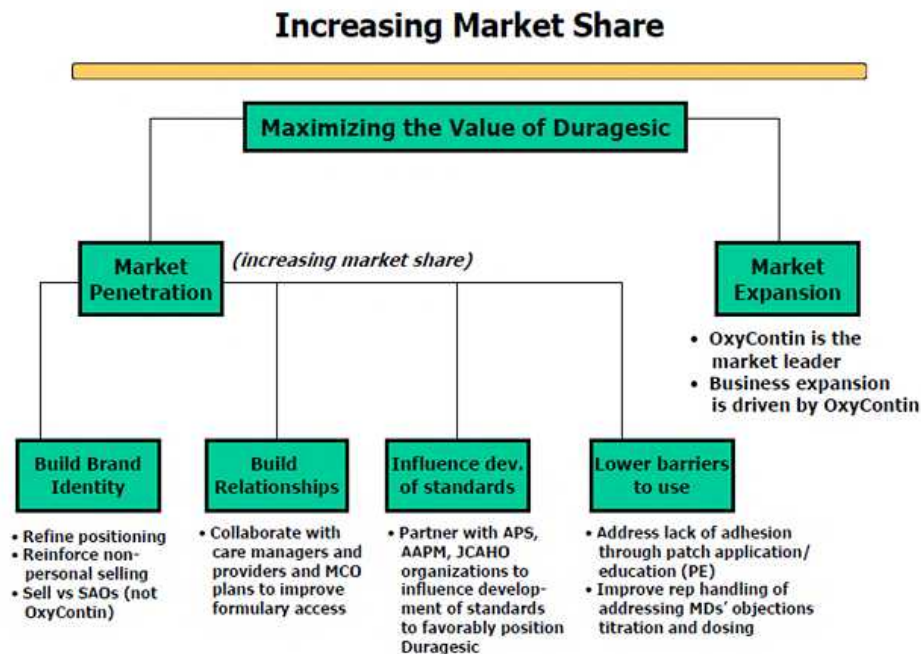
In April of 2001, Purdue created a Partners Against Pain Advocacy Toolkit, essentially a guide to how to control the abuse message, and Janssen ended up with a copy. JAN-MS-00304077.

Purdue and Janssen also had contact through the "Pain Forum" meetings. In October 2002, a save the date for "Pain Forum II" meeting of DEA and industry leaders was sent out. JAN-MS-00386260; JAN-MS-00614872. The meeting was organized by Joranson of the Pain & Policy Studies Group and by Last Acts (RWJF). And in the summer of 2001, the DEA & Joranson had meetings with "select industry members" on OxyContin abuse issues, which resulted in the DEA consensus statement. JAN-MS-00386260.

"The chronic pain market has vastly expanded because of two primary players, Duragesic and Oxycontin." JAN-MS-00299220.

Janssen acknowledges that Oxycontin drives market growth, generally, and drives Duragesic growth, specifically. JAN-MS-00306767; JAN-MS-00299220; JAN-MS-00432716

(Kuntz). Janssen sought to drive patients & prescribers from short-acting opioids to long-acting opioids, like Duragesic. JAN-MS-00494171 at 14 (Moskovitz).

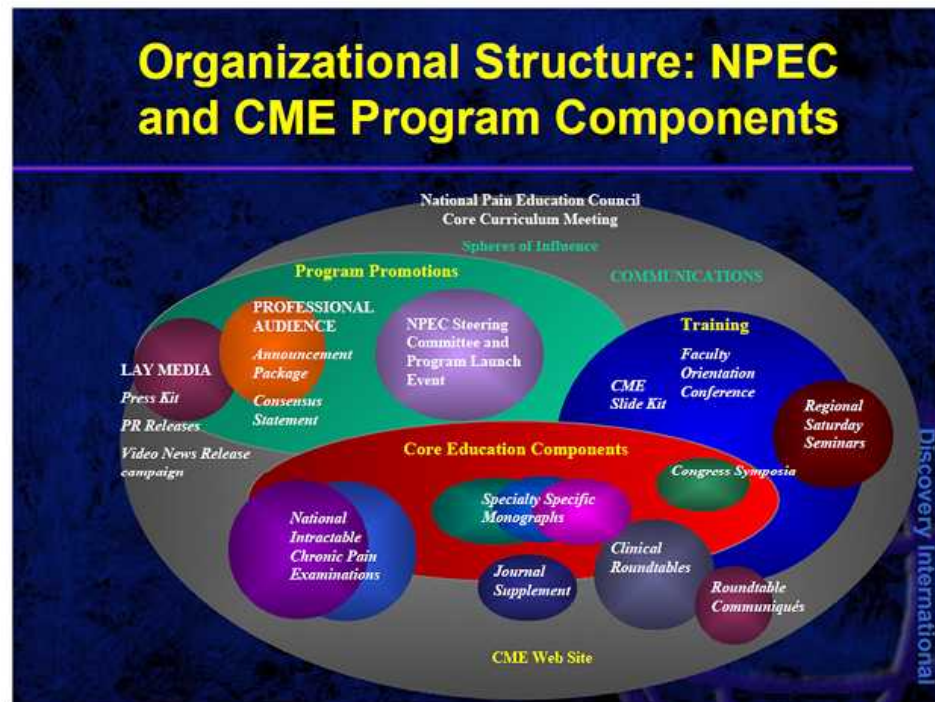


On November 11, 2001, Jeff Mathis wrote that "Oxycontin and Duragesic are responsible for growth [of the Strong Opioid Market]." JAN-MS-02531371. He placed growth at 21%. "Growth of OxyContin was only slowed by concerns over the abuse potential." JAN-MS-02531371. In another document created by McKinsey & Company for Janssen's Global Operations Team on Duragesic Disease Modeling, acknowledging that OxyContin created the market in low back pain, which is where Duragesic wants to position itself. JAN-MS-00432716 at 4. A Janssen request for research proposals tacitly acknowledges that competitor sales can expand the chronic pain market. JAN-MS-00305722. Further, a 2002 Duragesic business plan states that Purdue is an attractive co-promotion partner. JAN-MS-00310227 at -84.

Even when competing, Purdue recognized the companies helped each other: “We will produce and create programs that will generate interest and growth in Pain management, and so will [Janssen]. In some cases some of the things they do will help us, and vice-versa.” PPLPC009000079874.

Janssen spent millions creating the National Pain Education Council (“NPEC”) with the help of Discovery International (AKA: Discovery East, LLC) (“Discovery”) sometime around August 2001 as part of the Duragesic Tactical Plan. JAN-MS-00306713. According to an “Agency Performance Survey,” an internal review, Discovery became Janssen’s “medical education agency of record” in September 2000. JAN-MS-00781342. “The Discovery East team is dedicated to the overall management of the brand, not only execution of the actual tactics.” JAN-MS-00247190. Kathleen “Kati” Chupa, who looks to have been Discovery’s handler, deemed its programs “effective and aligned with brand strategies.” JAN-MS-00781342.

Janssen’s vision for the NPEC was comprehensive, as shown by the following slide:



JAN-MS-00306713. The organization was to be endorsed by APS, AAPM, and "other pertinent medical societies." JAN-MS-00306713. The timeline for the project can be found at JAN-MS-00314040.

Critically, the NPEC was to be (and was) co-chaired by Dr. Russell Portenoy (APS President) and Dr. Richard Payne, with numerous other doctors and a JCAHO representative sitting on its executive committee and peer review committee. JAN-MS-00306713. June Dahl of PPSG was also involved. According to January 2003 meeting notes, it appears that Drs. Payne and Portenoy were to be paid "\$15M" individually and "\$25M" to their respective institutions in honorarium. JAN-MS-00312977. The doctors also appear to have met with the DEA in their NPEC capacities. JAN-MS-00777576.

According to a Discovery presentation, its goals for NPEC were to:

- Drive healthcare providers to the NPEC website in 2002
- Initiate the positioning of the NPEC as the premier pain management education program for the medical community
- Position long-acting opioids as preferred therapy for the treatment of chronic pain
- Strengthen Janssen's positioning as a leader in pain management education

JAN-MS-00787624. A 2003 Tactical Plan shows the following NPEC Objectives:

- Establish website as a key educational resource for primary care physicians – specifically on the appropriate use of opioids for pain management
- Position as a referral site for pain specialists to encourage and facilitate education of the expanded pain management team
- Establish as an educational tool in fellowship and residency training programs
- Use as springboard for pain management franchise development
- Position Janssen as a leader in pain management

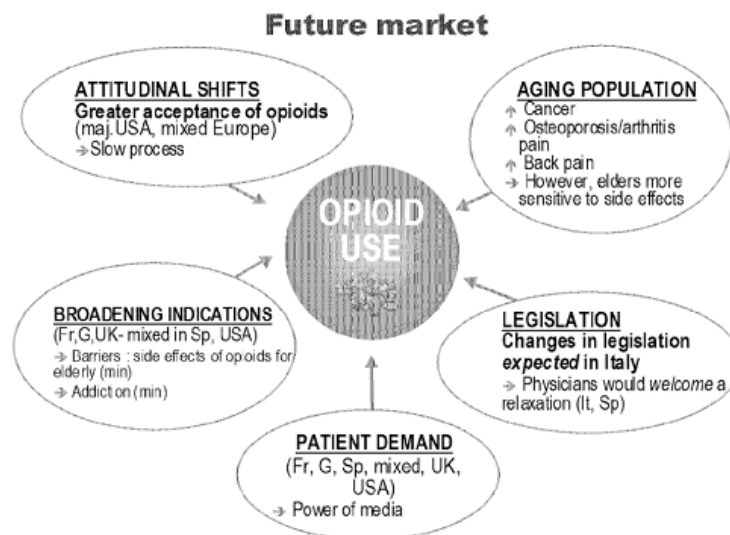
JAN-MS-00780331. An estimated budget for the year 2003 shows nearly \$10M on NPEC programs. JAN-MS-00306772.

Internally, the NPEC was certainly a top “strategy and tactic” for “position[ing] Duragesic as the optimal LAO choice for non-malignant and malignant pain.” JAN-MS-00494171 at 10-11. And Kati Chmonitorupa was clear that Discovery's work is one method of “leveraging Duragesic dollars for the franchise.” JAN-MS-00726338 (Blockinger).

A website, www.npecweb.org, was eventually created. See https://web.archive.org/web/*/http://npecweb.org/. Janssen disclosed that it funded the NPEC website, it also says that all content is created by the co-chairs. February 2002 meeting notes indicate that that materials for the NPEC program were “derived” from an outline written by Dr. Portenoy and Payne, approved by Discovery and reviewed by Janssen. JAN-MS-00312347. The same notes demonstrate that monographs were written by writers directed by Discovery. JAN-MS-00312347.

A July 2003 presentation lays out how Discovery assisted Janssen in promoting Duragesic

at APS, AAPM, and ASPMN symposiums. JAN-MS-02760144. Around the same time, other non-Discovery-related presentations clearly demonstrate that Janssen viewed attitudinal shifts and broadened indications, among other factors, as contributing to increased opioid use/sales:



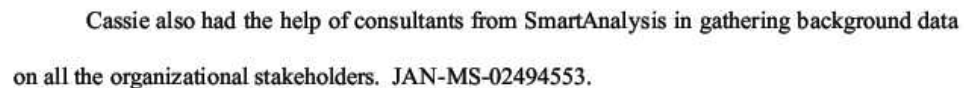
JAN-MS-00371431 (2002 Taylor Nelson Sofres Report on Duragesic Lifecycle).



JAN-MS-00306755 (2001 Pain Franchise Review).

In June 2001, Janssen agreed to contribute \$50,000 to fund, with other manufacturers, an “Advanced Pain Management Certification Program” in Florida. JAN-MS-01144712. The program was targeted at pharmacists, and it was seen as a way to overcome their resistance to dispensing opioids. JAN-MS-01144712. The licensing program was viewed as “the first of its kind” and probable to “serve as a reference point for other such programs.” JAN-MS-01144712. In the same email, it is mentioned that the program is consistent with JCAHO objectives “i.e., fifth vital sign.” A 1997 survey funded by the Robert Wood Johnson Foundation that developed the pain 2001 JCAHO standards. David Baker, MD, MPH, *The Joint Commission's Pain Standards: Origins & Evolution*, THE JOINT COMMISSION (May 5, 2017), https://www.jointcommission.org/assets/1/6/Pain_Std_History_Web_Version_05122017.pdf.

From February 2009 AAPM Corporate Council meeting notes, it appears that Cassie Hallberg, Director of Analgesic Stakeholder Relations for Janssen (now a former employee) attended an AAPM meeting where she agreed to identify key professional and patient pain associations and to “map” out those stakeholders and lines of influence to each in order to help AAPM “start a movement.” JAN-MS-00929254. This occurred around the time the REMS Task Force was active. Cassie Hallberg created the “Influence Map,” below. JAN-MS-02494558.



Executive Summary
SMARTANALYST
INTELLIGENT INSIGHTS. SMART RESULTS.

Pain Association	Focus of Mission	Website	Newsletter	Geographic Presence	Number of Members
American Pain Society	High Focus on Pain Treatment <ul style="list-style-type: none"> To increase knowledge of pain and transform public policy and clinical practice to reduce pain-related suffering. 			National (six regional sections)	Over 3,000 (including health professionals, basic scientists, policy makers, and lawyers)
American Pain Foundation	High Focus on Pain Treatment <ul style="list-style-type: none"> To improve the quality of life of people with pain 			National	80,000 (including patients, families and healthcare providers)
American Chronic Pain Association	High Focus on Pain Treatment <ul style="list-style-type: none"> To facilitate peer support and education for individuals with chronic pain and their families. To raise awareness among the health care community, policy makers, and the public at large about issues of living with chronic pain. 			International (more than 800 chapters)	NA
American Academy of Pain Medicine	High Focus on Pain Treatment <ul style="list-style-type: none"> To advance the specialty of Pain Medicine and the comprehensive care of patients with pain. 			National (four state Chapters)	Over 1,300
Alliance of State Pain Initiatives	High Focus on Pain Treatment <ul style="list-style-type: none"> To ensure that peoples' lives are not overpowered by pain. 			National (19 state pain initiatives)	NA

 Source: SmartAnalyst

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Cassie Hallberg also prepared a list of influential associations in each region of the country. JAN-MS-02494558 (Central Region – others attached to JAN-MS-02494552).

Plaintiff reserves the right to supplement or amend its response, and this issue may be the subject of fully-supported and detailed expert witness opinion(s).

Interrogatory No. 2

Identify each entity or natural person, including without limitation healthcare providers, patients, addiction treatment specialists, alleged key opinion leaders (as that term is used throughout the Complaint), alleged front groups, or any other third party, from whom Plaintiff received or attempted to obtain documents, testimony, sworn affidavits, or any other form of information in connection with Plaintiff's investigation of any Defendant's advertising or

marketing of opioids, or otherwise in connection with this litigation, and include in the response identification of all information sought or received from each entity or natural person.

Response:

Plaintiff repeats and reasserts its prior objections and adopts its prior responses to this Interrogatory. Plaintiff objects to this Interrogatory as overly broad, vague and ambiguous in that it fails to adequately or specifically define the term “entity or natural person” from whom each Plaintiff received information, and Plaintiff therefore will construe the term to exclude entities and natural persons who are part of the subject Plaintiff’s governmental structure. Plaintiff also objects to this Interrogatory on the grounds that it calls for production of information subject to the work-product doctrine, especially to the extent the Interrogatory seeks the identification of entities and natural persons from whom Plaintiff “attempted” to obtain information in furtherance of Plaintiff’s “investigation.” Disclosure of such information necessarily would reveal Plaintiff’s and its counsel’s mental impressions and legal strategies formed in anticipation of this litigation, and is therefore objectionable. Lastly, discovery continues and Plaintiff will produce a trial witness list and expert reports pursuant to the scheduling order in this case and the Federal Rules of Civil Procedure.

Notwithstanding and without waiving all objections, Plaintiff responds:

Name	Title	General Description
Dr. William Reed	Doctor	Visited by drug reps: Nucynta, Purdue, Actiq, Opana, Kadian
Dr. William Lonsdorf	Doctor	Visited by Purdue, Opana, Nucynta,
Dr. Kendrick Bashor	Doctor	Visited by drug reps: Purdue
Dr. Michael Louwers	Doctor	Visited by drug reps: Purdue, Xtampza, Nucynta, Actiq/Fentora
Dr. Syed Ali	Doctor	Visited by drug reps: Purdue, Xtampza, Nucynta-Janssen/Depomed, Teva, Subsys, Endo, Cephalon, Xalgo, Kadian, Insys

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Name	Title	General Description
Dr. Clayton Seiple	Doctor	Visited by drug reps: Purdue. Was a speaker for Endo, Depomed (Nucynta)
Bernie Rochford	Executive Vice President of Administrative Services and Business Relations, Oriana House	Treatment center for those suffering from OUD, knowledgeable on trends, prevalence and impact of opioids
Galen Sievert	Clinical Supervisor, Mature Services	Treatment center for those suffering from OUD, knowledgeable on trends, prevalence and impact of opioids
Laura Kidd	Behavioral Health Clinical Coordinator, AxessPointe Community Health Center at Arlington	Treatment center for those suffering from OUD, knowledgeable on trends, prevalence and impact of opioids
James Orlando	President of Summit Psychological Associates	Treatment center for those suffering from OUD, knowledgeable on trends, prevalence and impact of opioids
Brittney Becker	Doctor, Community Health Center	Treatment center for those suffering from OUD, knowledgeable on trends, prevalence and impact of opioids
Michael M. Hughes	President, Summa Health System, Barberton Campus	Illnesses related to opioid use; visited by drug reps: Purdue
Joseph P. Myers	Doctor, Vice President of Medical Affairs, Summa Barberton and Summa Wadsworth-Rittman Hospitals	Illnesses related to opioid use
Roslyn Greene	Family member	Personal loss
Charlene Maxen	Pediatric oncologist nurse, Akron Children's Hospital	Personal loss
Travis and Shelly Bornstein	Family member	Personal loss
Dr. Tony Lababidi	Doctor	Visited by drug reps: Purdue, Endo, Janssen
Dr. Laura Novak	Doctor	Visited by drug reps: Purdue
Dr. Adolph Harper	Doctor	Visited by drug reps
Reba McCray	Family member	Personal loss
Josh Vandergriff	Family member	Personal loss
Dr. Ann DiFrangia	Specializes in treatment of substance use disorders	
Aimee Wade	Family member	Personal loss
Dr. Nicole Labor	Family member	Personal loss & addiction

Name	Title	General Description
Greg McNeil	Family member	Personal loss

Plaintiff also refers Defendants to its responses to Interrogatory No 5. Plaintiff reserves the right to amend, supplement or modify this response as discovery proceeds.

Pursuant to Federal Rule of Civil Procedure 33(d), Plaintiffs identify the documents concerning front groups listed on Exhibit 2A.

Plaintiff reserves the right to supplement or amend its response, and this issue may be the subject of fully-supported and detailed expert witness opinion(s).

Interrogatory No. 3:

Identify any doctors, addiction treatment specialists, healthcare providers, and law enforcement and public health officials who Plaintiff contends agree with the proposition that prescription opioids have caused or contributed to the opioid epidemic (as that term is used throughout the Complaint).

Response:

Plaintiff repeats and reasserts its prior objections and adopts its prior responses to this Interrogatory. Plaintiff objects to this Interrogatory as vastly overly broad and unduly burdensome. Plaintiff objects to the extent it requests “any” doctors, addiction treatment specialists, health care providers and law enforcement and public health officials that agree with the proposition that prescription opioids have caused or contributed to the opioid epidemic. Plaintiff further responds that this Interrogatory is contention discovery more appropriately answered once discovery is completed, or until a pre-trial conference. *See* FRCP 33(a)(2). Therefore, Plaintiff will construe this phrase to refer to any such contentions in Plaintiff’s Second Amended Complaint.

Plaintiff objects to this Interrogatory as vague, ambiguous and calling for speculation about the beliefs or opinions of individual third parties regarding opioids. There is a vast amount of

peer-reviewed scientific literature, testimony before public entities, information in the public domain, testimony and evidence in this case equally available to Defendants, which may provide the answer, at least in large part, to Defendants' Interrogatory. Notwithstanding and without waiving all objections, Plaintiff's responsive persons include, but are not limited to:

Vivek H. Murthy, M.D., M.B.A., 19th U.S. Surgeon General;
Centers for Disease Control and Prevention;
National Institute on Drug Abuse;
Theodore J. Cicero, M.D.;
Robert M. Califf, M.D.;
Russell Portenoy, M.D.;
Thomas Gilson, M.D.;
Andrew Kolodny, M.D.;
Special Agent David Schiller;
Thomas R. Frieden, M.D.;
Wanda Barfield, M.D.;
Cheryl Broussard, Ph.D.;
Kimberly Yonkers, M.D.;
Stephen Patrick, M.D., M.P.H., M.S.;
Pamela Hyde, J.D.;
Nora Volkow, M.D.;
George Koob, Ph.D.;
Lauren Thomas, M.D.;
Doug Smith, M.D., Summit County Medical Director
Robert Anderson, Centers for Disease Control and Prevention
Kimberly Patton LISW-S, LICDC, Summit County ADM
Jackie Pollard, L.S.W., Asst. Community Health Director, Summit County
Donna Skoda, M.S., R.D., L.D., Health Commissioner, Summit County
Gerald Craig, Executive Director, Summit County ADM
Tonya Block, L.S.W., M.S.W, Asst. Health Commissioner, Summit County
Matt Paolino, Captain, Summit County Sheriff's Office
Michael Shearer, Captain, Narcotics Subdivision, Akron Police Department

Charles Brown, Deputy Mayor of Akron Public Safety
Shane Barber, Jail Admin
Kenneth Ball, Chief of Police
Expert witnesses to be named.

Plaintiff identifies the public health community in Summit County, Cuyahoga County and the State of Ohio, and expert witnesses in this case. Plaintiff reserves the right to supplement or amend its response as expert discovery commences, and this issue may be the subject of fully-supported and detailed expert witness opinion(s).

Interrogatory No. 5:

Identify and describe all alleged key opinion leaders (as that term is used throughout the Complaint), alleged front groups, and other third parties with whom any Defendant allegedly conspired or acted in concert in furtherance of the alleged misconduct described in the Complaint, including the identity of each Defendant that allegedly conspired and all facts supporting Plaintiff's contention that such Defendant(s) did so.

Response:

Plaintiff repeats and reasserts its prior objections and adopts its prior responses to this Interrogatory. Plaintiff objects to this Interrogatory as overly broad and unduly burdensome in that it seeks information that is uniquely in Defendants' possession, and thus imposes an undue burden and unnecessary expense on Plaintiff. Plaintiff further objects to this Request as vague, overly broad and unduly burdensome to the extent it requests Plaintiff to identify and describe all key opinion leaders, alleged front groups and other third parties. Further objecting, the Interrogatory contains a reference to several ambiguous phrases, namely, "alleged front groups," "allegedly conspired," "acted in concert," "in furtherance of," and "alleged misconduct".

Plaintiff responds that this Interrogatory is contention discovery more appropriately answered once discovery is complete. *See* FRCP 33(a)(2). Plaintiff responds discovery continues

and Plaintiff will produce a trial witness list and expert reports pursuant to the scheduling order in this case and the Federal Rules of Civil Procedure. Plaintiff also refers Defendants to Plaintiff's Second Amended Complaint, which identifies key opinion leaders, alleged front groups, and other third parties acting in concert with Defendants. Finally, Plaintiff incorporates by reference its responses to Manufacturer Interrogatory Nos. 1, 2 & 29.

Notwithstanding and without waiving all objections, Plaintiff responds as follows:

Name	Title	Facts Alleged in Support
Russell Portenoy	Doctor, Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York	<p>In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."</p> <p>Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:</p> <p><i>The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the</i></p>

Name	Title	Facts Alleged in Support
		<p><i>development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.</i></p> <p>According to Dr. Portenoy, the foregoing problems could constitute “compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain.”</p> <p>Despite having taken this position on long-term opioid treatment, Dr. Portenoy ended up becoming a spokesperson for Purdue and other Marketing Defendants, promoting the use of prescription opioids and minimizing their risks. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, described him “lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a compelling message: ‘Docs have been letting patients suffer; nobody really gets addicted; it’s been studied.’”</p> <p>As one organizer of CME seminars who worked with Portenoy and Purdue pointed out, “had Portenoy not had Purdue’s money behind him, he would have published some papers, made some speeches, and his influence would have been minor. With Purdue’s millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified.”</p> <p>Dr. Portenoy was also a critical component of the Marketing Defendants’ control over their Front Groups. Specifically, Dr. Portenoy sat as a Director on the board of the APF. He was also the President of the APS.</p>

Name	Title	Facts Alleged in Support
		<p>In recent years, some of the Marketing Defendants' KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature. Dr. Portenoy has now admitted that he minimized the risks of opioids, and that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." He mused, "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did . . ."</p> <p>In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not "real" and left real evidence behind:</p> <p style="padding-left: 40px;">I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, <i>none of which represented real evidence</i>, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. <i>In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind.</i></p> <p>Several years earlier, when interviewed by journalist Barry Meier for his 2003 book, <i>Pain Killer</i>, Dr. Portenoy was more direct: "It was pseudoscience. I guess I'm going to have always to live with that one."</p>

Name	Title	Facts Alleged in Support
Lynn Webster	Doctor, co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah	<p>Another Key Opinion Leader, Dr. Lynn Webster, was the co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a Front Group that ardently supports chronic opioid therapy. He is a Senior Editor of <i>Pain Medicine</i>, the same journal that published Endo's special advertising supplements touting Opana ER.</p> <p>Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly \$2 million from Cephalon).</p> <p>Dr. Webster created and promoted the Opioid Risk Tool ("ORT"), a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's ORT appear on, or are linked to, websites run by Endo, Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, <i>Managing Patient's Opioid Use: Balancing the Need and the Risk</i>. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors in Plaintiffs' communities.</p> <p>Dr. Webster was himself tied to numerous overdose deaths. He and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the Marketing Defendants' promotional messages, Dr. Webster apparently</p>

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Name	Title	Facts Alleged in Support
		<p>believed the solution to patients' tolerance or addictive behaviors was more opioids: he prescribed staggering quantities of pills.</p> <p>At an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled, "Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results." The presentation's agenda description states: "Most patients with chronic pain experience episodes of breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment." The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the "[i]nterim results of this study suggest that FEBT is safe and well-tolerated in patients with chronic pain and BTP." This CME effectively amounted to off-label promotion of Cephalon's opioids—the only drugs in this category—for chronic pain, even though they were approved only for cancer pain.</p> <p>Cephalon sponsored a CME written by Dr. Webster, <i>Optimizing Opioid Treatment for Breakthrough Pain</i>, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.</p>

Name	Title	Facts Alleged in Support
Perry Fine	Doctor, co-chair of APS/AAPM Opioid Guideline Panel	<p>Dr. Perry Fine's ties to the Marketing Defendants are well documented. He has authored articles and testified in court cases and before state and federal committees, and he, too, has argued against legislation restricting high-dose opioid prescription for non-cancer patients. He has served on Purdue's advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS/AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was on the board of directors of APF.</p> <p>Multiple videos feature Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith for pain did not make her an addict before her death.</p> <p>He has also acknowledged having failed to disclose numerous conflicts of interest. For example, Dr. Fine failed to fully disclose payments received as required by his employer, the University of Utah—telling the university that he had received under \$5,000 in 2010 from J&J for providing “educational” services, but J&J's website states that the company paid him \$32,017 for consulting, promotional talks, meals and travel that year.</p> <p>Dr. Fine and Dr. Portenoy co-wrote <i>A Clinical Guide to Opioid Analgesia</i>, in which they downplayed the risks of opioid treatment, such as respiratory depression and addiction:</p> <p style="padding-left: 40px;">At clinically appropriate doses, . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk.</p> <p>Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short</p>

Name	Title	Facts Alleged in Support
		<p>period (i.e., for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.</p> <p>In November 2010, Dr. Fine and others published an article presenting the results of another Cephalon-sponsored study titled “Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study.” In that article, Dr. Fine explained that the 18-month “open-label” study “assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for noncancer pain.” The article acknowledged that: (a) “[t]here has been a steady increase in the use of opioids for the management of chronic noncancer pain over the past two decades”; (b) the “widespread acceptance” had led to the publishing of practice guidelines “to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain”; and (c) those guidelines lacked “data assessing the long-term benefits and harms of opioid therapy for chronic pain.”</p> <p>The article concluded: “[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable.” They also conclude that the number of abuse-related events was “small.”</p> <p>Multiple videos feature Dr. Fine delivering educational talks about the drugs. In one video from 2011 titled “Optimizing Opioid Therapy,” he sets forth a “Guideline for Chronic Opioid Therapy” discussing “opioid rotation” (switching from one opioid to another) not only for cancer patients, but for non-cancer patients, and suggests it may take four or five switches over a person’s “lifetime” to manage pain. He states the “goal is to</p>

Name	Title	Facts Alleged in Support
		<p>improve effectiveness which is different from efficacy and safety.” Rather, for chronic pain patients, effectiveness “is a balance of therapeutic good and adverse events <i>over the course of years</i>.” The entire program assumes that opioids are appropriate treatment over a “protracted period of time” and even over a patient’s entire “lifetime.” He even suggests that opioids can be used to treat <i>sleep apnea</i>. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with “tools,” but leaves that for “a whole other lecture.”</p>
Scott Fishman	Doctor, served as a board member of APF and president of AAPM	<p>Dr. Scott Fishman is a physician whose ties to the opioid drug industry are legion. He has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received “market rate honoraria.” As discussed below, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Marketing Defendants. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in the <i>Journal of the American Medical Association</i> titled “Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion.”</p> <p>In 2007, Dr. Fishman authored a physician’s guide on the use of opioids to treat chronic pain titled <i>Responsible Opioid Prescribing</i>, which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.</p> <p>In 2012, Dr. Fishman updated the guide and continued emphasizing the “catastrophic” “under-treatment” of pain and the “crisis” such under-treatment created:</p> <p>Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop</p>

Name	Title	Facts Alleged in Support
		<p>prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, it's critical to remember that the problem of unrelieved pain remains as urgent as ever.</p> <p>The updated guide still assures that "[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and noncancer origins."</p> <p>In another guide by Dr. Fishman, he continues to downplay the risk of addiction: "I believe clinicians must be very careful with the label 'addict.' I draw a distinction between a 'chemical coper' and an addict." The guide also continues to present symptoms of addiction as symptoms of "pseudoaddiction."</p>
American Pain Foundation ("APF")		<p>The most prominent of the Front Groups was APF. While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from defendants Purdue, Endo, Janssen and Cephalon. APF received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. Endo was APF's largest donor and provided more than half of its \$10 million in funding from 2007 to 2012.</p> <p>For example, APF published a guide sponsored by Cephalon and Purdue titled <i>Treatment Options: A Guide for People Living with Pain</i>, and distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report. This guide contains multiple misrepresentations regarding opioid use, which are discussed below.</p>

Name	Title	Facts Alleged in Support
		<p>APF also developed the National Initiative on Pain Control (“NIPC”), which ran a facially unaffiliated website, <i>www.PainKnowledge.com</i>. NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. NIPC published unaccredited prescriber education programs (accredited programs are reviewed by a third party and must meet certain requirements of independence from pharmaceutical companies), including a series of “dinner dialogues.” But it was Endo that substantially controlled NIPC, by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. Endo’s control of NIPC was such that Endo listed it as one of its “professional education initiative[s]” in a plan Endo submitted to the FDA. Yet, Endo’s involvement in NIPC was nowhere disclosed on the website pages describing NIPC or <i>www.PainKnowledge.com</i>. Endo estimated it would reach 60,000 prescribers through NIPC.</p> <p>APF was often called upon to provide “patient representatives” for the Marketing Defendants’ promotional activities, including for Purdue’s “Partners Against Pain” and Janssen’s “Let’s Talk Pain.” Although APF presented itself as a patient advocacy organization, it functioned largely as an advocate for the interests of the Marketing Defendants, not patients. As Purdue told APF in 2001, the basis of a grant to the organization was Purdue’s desire to strategically align its investments in nonprofit organizations that share [its] business interests.</p> <p>In practice, APF operated in close collaboration with Defendants, submitting grant proposals seeking to fund activities and publications suggested by Defendants and assisting in marketing projects for Defendants.</p> <p>This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to</p>

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Name	Title	Facts Alleged in Support
		<p>provide consulting services on its marketing initiatives. Purdue and APF entered into a “Master Consulting Services” Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF’s work related to a specific promotional project. Moreover, based on the assignment of particular Purdue “contacts” for each project and APF’s periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF’s funding) for any reason. Even for projects not produced during the terms of this Agreement, the Agreement demonstrates APF’s lack of independence and willingness to harness itself to Purdue’s control and commercial interests, which would have carried across all of APF’s work.</p> <p>APF’s Board of Directors was largely comprised of doctors who were on the Marketing Defendants’ payrolls, either as consultants or speakers at medical events. The close relationship between APF and the Marketing Defendants demonstrates APF’s clear lack of independence, in its finances, management, and mission, and its willingness to allow Marketing Defendants to control its activities and messages supports an inference that each Defendant that worked with it was able to exercise editorial control over its publications—even when Defendants’ messages contradicted APF’s internal conclusions. For example, a roundtable convened by APF and funded by Endo also acknowledged the lack of evidence to support chronic opioid therapy. APF’s formal summary of the meeting notes concluded that: “[An] important barrier[] to appropriate opioid management [is] the lack of confirmatory data about the long-term safety and efficacy of opioids in non-cancer chronic pain, amid cumulative clinical evidence.”</p>

Name	Title	Facts Alleged in Support
		<p>In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately." Without support from Marketing Defendants, to whom APF could no longer be helpful, APF was no longer financially viable.</p>
<p>American Academy of Pain Medicine and American Pain Society ("AAPM" and "APS," respectively)</p>		<p>AAPM and APS are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Russell Portenoy, who was also a spokesperson for Purdue. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.</p> <p>AAPM's corporate council includes Purdue, Depomed, Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Dr. Scott Fishman ("Fishman") (2005), Dr. Perry G. Fine ("Fine") (2011) and Dr. Lynn R. Webster ("Webster") (2013), all of whose connections to the opioid manufacturers are well-documented as set forth below.</p> <p>Fishman, who also served as a KOL for Marketing Defendants, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."</p> <p>AAPM received over \$2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose</p>

Name	Title	Facts Alleged in Support
		<p>members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations.</p> <p>AAPM describes the annual event as an “exclusive venue” for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids—37 out of roughly 40 at one conference alone.</p> <p>AAPM's staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.</p> <p>AAPM and APS issued their own guidelines in 2009 (“2009 Guidelines”). AAPM, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOL Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue. Of these individuals, six received support from Purdue, eight from Teva, nine from Janssen, and nine from Endo.</p> <p>One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache</p>

Name	Title	Facts Alleged in Support
		<p>& Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.</p> <p>Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who also served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.</p> <p>The 2009 Guidelines have been a particularly effective channel of deception. They have influenced not only treating physicians, but also the scientific literature on opioids; they were reprinted in the <i>Journal of Pain</i>, have been cited hundreds of times in academic literature, were disseminated during the relevant period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Marketing Defendants promoted opioids, whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these guidelines. For that reason, the CDC has recognized that treatment guidelines can "change prescribing practices."</p> <p>The 2009 Guidelines are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain.</p> <p>The Marketing Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development of the Guidelines or their financial backing of the authors</p>

Name	Title	Facts Alleged in Support
		of these Guidelines. For example, a speaker presentation prepared by Endo in 2009 titled <i>The Role of Opana ER in the Management of Moderate to Severe Chronic Pain</i> relies on the AAPM/APS Guidelines while omitting their disclaimer regarding the lack of evidence for recommending the use of opioids for chronic pain.
Federation of State Medical Boards ("FSMB")		<p>The FSMB is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.</p> <p>The FSMB finances opioid- and pain-specific programs through grants from Defendants.</p> <p>Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies." The 1998 Guidelines that the pharmaceutical companies helped author taught not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option.</p> <p>A 2004 iteration of the 1998 Guidelines and the 2007 book, <i>Responsible Opioid Prescribing</i>, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in Summit County.</p> <p>FSMB's 2007 publication <i>Responsible Opioid Prescribing</i> was backed largely by drug manufacturers, including Purdue, Endo and Cephalon. The publication also received support from the American Pain Foundation and the American Academy of Pain Medicine. The publication was written by Dr. Fishman, and Dr. Fine served on the Board of Advisors. In all,</p>

Name	Title	Facts Alleged in Support
		<p>163,131 copies of <i>Responsible Opioid Prescribing</i> were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as “the leading continuing medical education (CME) activity for prescribers of opioid medications.” This publication asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient..</p> <p>The Marketing Defendants relied on the 1998 Guidelines to convey the alarming message that “under-treatment of pain” would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors’ fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.</p>
The Alliance for Patient Access (“APA”)		<p>Founded in 2006, the APA is a self-described patient advocacy and health professional organization that styles itself as “a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care.” It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006. As of June 2017, the APA listed 30 “Associate Members and Financial Supporters.” The list includes J&J, Endo, Mallinckrodt, Purdue and Cephalon.</p> <p>APA’s board members have also directly received substantial funding from pharmaceutical companies. For instance, board vice president Dr. Srinivas Nalamachu (“Nalamachu”), who practices in Kansas, received more than \$800,000</p>

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Name	Title	Facts Alleged in Support
		<p>from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids’ side effects, including from defendants Endo, Insys, Purdue and Cephalon. Nalamachu’s clinic was raided by FBI agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys. Other board members include Dr. Robert A. Yapundich from North Carolina, who received \$215,000 from 2013 through 2015 from pharmaceutical companies, including payments by defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than \$240,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received \$153,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Purdue, Insys, Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received \$700,000 between 2013 and 2015 from pharmaceutical companies.</p> <p>Among its activities, APA issued a “white paper” titled “Prescription Pain Medication: Preserving Patient Access While Curbing Abuse.” Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:</p> <p style="padding-left: 40px;">Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.</p> <p style="text-align: center;">* * *</p>

Name	Title	Facts Alleged in Support
		<p>In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . . .</p> <p>We cannot merely assume that these programs will reduce prescription pain medication use and abuse.</p> <p>The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:</p> <p>Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.</p> <p>In addition, in an echo of earlier industry efforts to push back against what they termed “opiophobia,” the white paper laments the stigma associated with prescribing and taking pain medication:</p> <p>Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can’t get their</p>

Name	Title	Facts Alleged in Support
		<p>prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong—or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management—a situation fueled by the numerous regulations and fines that surround prescription pain medications.</p> <p>In conclusion, the white paper states that “[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs.”</p> <p>The APA also issues “Patient Access Champion” financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a \$7.8 million donation from unnamed donors. While the awards are ostensibly given for protecting patients’ access to Medicare, and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they appear to be given to provide cover to and reward members of Congress who have supported the APA’s agenda.</p> <p>The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the “suspicious orders” provision of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 <i>et seq.</i> (“CSA” or “Controlled Substances Act”). The AAPM is also a signatory to this letter. An internal U.S. Department of Justice (“DOJ”) memo stated that the proposed bill “could actually result in increased diversion, abuse, and public health and safety consequences” and, according to DEA chief administrative law judge John J.</p>

Name	Title	Facts Alleged in Support
		Mulrooney ("Mulrooney"), the law would make it "all but logically impossible" to prosecute manufacturers and distributors, like the defendants here, in the federal courts. The bill passed both houses of Congress and was signed into law in 2016.
The U.S. Pain Foundation ("USPF")		The USPF was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. The USPF was one of the largest recipients of contributions from the Marketing Defendants, collecting nearly \$3 million in payments between 2012 and 2015 alone. The USPF was also a critical component of the Marketing Defendants' lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertises its ties to the Marketing Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil (<i>i.e.</i> , Janssen), and Mallinckrodt as "Platinum," "Gold," and "Basic" corporate members. Industry Front Groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.
American Geriatrics Society ("AGS")		The AGS was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. AGS was a large recipient of contributions from the Marketing Defendants, including Endo, Purdue and Janssen. AGS contracted with Purdue, Endo and Janssen to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (<i>The Management of Persistent Pain in Older Persons</i> , hereinafter "2002 AGS Guidelines") and 2009 (Pharmacological Management of Persistent Pain in Older Persons, hereinafter "2009 AGS Guidelines"). According to news reports, AGS has received at least \$344,000 in funding from opioid manufacturers since 2009. AGS's complicity in the common purpose with the Marketing Defendants is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive-up front funding from drug companies, which would suggest drug

Name	Title	Facts Alleged in Support
		<p>company influence, but would instead accept commercial support to disseminate pro-opioid publications.</p> <p>The 2002 AGS Guidelines, in part, were based on the false notions that the risk of addiction was low amongst older populations and alternative forms of pain relief pose greater risks than opioids. The guidelines stated, “True addiction (drug craving and continued use despite known harms) in older patients with persistent pain syndromes is <i>probably</i> rare in comparison with the known prevalence of undertreated debilitating pain.” and “... [t]he chronic use of opioids for persistent pain or some other analgesic strategies may have fewer life-threatening risks than does the long-term daily use of high-dose nonselective NSAIDs.”</p> <p>The 2009 AGS Guidelines recommended that “[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy.” The panel made “strong recommendations” in this regard despite “low quality of evidence” and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. These Guidelines further recommended that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.” These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited over 1,833 times in Google Scholar (which allows users to search scholarly publications that would have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year.</p> <p>Representatives of the Marketing Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would</p>

Name	Title	Facts Alleged in Support
		<p>support projects conceived as a result of these communications.</p> <p>Members of AGS Board of Directors were doctors who were on the Marketing Defendants' payrolls, either as consultants or speakers at medical events. As described below, many of the KOLs also served in leadership positions within the AGS.</p>
Pain Care Forum		<p>The PCF is an informal group of pharmaceutical companies, trade associations like the HDA (among others), and pain advocacy organizations, and other members that was started by Purdue's Burt Rosen. The group was formed with the purpose to unify efforts of companies and organizations seeking to advance pro-pain educational, marketing, regulatory, and other legislative agendas. Defendants controlled the PCF, served on numerous PCF task forces and committees, attended monthly PCF meetings together to for their joint strategies, held regular conference calls to discuss pain-related issues, and collaborated and coordinated efforts to counter regulatory and legislative threats to the Defendants manufacturing and distribution businesses..</p> <p>Because the PCF is not a formal business organization with a board of directors or employees and was, rather, composed only of members who wished to work together, the Defendants and members of the PCF were able to exert complete control over the coordinated activities of the PCF.</p> <p>The PCF acted on behalf of Defendants and other PCF members as an echo chamber, holding itself out as an independent third party, but mirroring Defendant communications and to, and interactions with, government officials and agencies. Additionally, acting on Defendants' direction and behalf, the PCF coordinated and collaborated with various trade associations, pain advocacy organizations, and various medical associations to build coalitions or group action supporting issues effecting Defendants' distribution activities that are governed by the obligation to maintain systems to</p>

Name	Title	Facts Alleged in Support
		prevent diversion by identifying, reporting and halting suspicious orders. As but one example, the PCF invited its member – HDA – to educate the PCF members about the HDA’s model industry compliance guidelines. Documents evidencing the activities of the PCF are included in the attached Manufacturer Interrogatory Appendix 5A.
Anti-Diversion Industry Working Group		<p>The ADIWG was originally formed by Mallinckrodt and a select group of distributors and other membership. Members of the ADIWG attended meetings, held conference calls, and coordinated via email communications on issues related to diversion and suspicious order monitoring. The ADIWG furthered the common purpose of the Opioid Marketing and Supply Chain Enterprises by collaborating on the production and dissemination of a “training” video that placed the burden to identify and report suspicious orders solely on pharmacies and pharmacists and their corresponding obligation to spot red flags for diversion. In addition to the ADIWG video and the work that was necessary to create it, members of the ADIWG discussed suspicious order monitoring and diversion, including company-specific SOM policies and procedure. The ADIWG was eventually sidelined because of purported concerns about a lack of funding and overlap with other Defendant-allied groups, but it was also clear that members of the ADIWG did not want to create an articulation of suspicious order monitoring policies that could be held against ADIWG members.</p> <p>Because the ADIWG is not a formal business organization with a board of directors or employees and was, rather, composed only of members who wished to work together, the Defendants and members of the ADIWG were able to exert complete control over the coordinated activities of the ADIWG.</p> <p>Documents evidencing the activities of the ADIWG are included in the attached Manufacturer Interrogatory Appendix 5B.</p>

Name	Title	Facts Alleged in Support
New Jersey Pharmaceutical Working Group ("NJPIG")		<p>The NJPIG is a group of Defendants that began working together after the NJPIG was created by Purdue's Jack Crowley in 2008. Like the PCF, the NJPIG is not a formal business entity. But, the Defendants' participation in this group is ongoing. While the NJPIG initially focused on manufacturer regulatory compliance issues, including suspicious order monitoring, the group has grown to include Distributor Defendants as well as Manufacturer Defendants. Regular meetings, conference calls, and emails were used by the NJPIG member Defendants to coordinate and share information related to DEA enforcement actions, quota application issues, suspicious order monitoring requirements, and other legislative and regulatory issues. The NJPIG, like the PCF, was controlled exclusive and completely by its member Defendants. The NJPIG also coordinated and collaborated with other informal industry groups, trade associations, and pain advocacy organizations to further Defendants manufacturing and supply chain businesses: including, but not limited to, lobbying and advocating against DEA quota measures aimed at reducing diversion, coordinating efforts to prevent hydrocodone being rescheduled as a Class II controlled substance, and supporting regulatory efforts aimed at undercutting DEA's abilities to fight diversion.</p> <p>Because the NJPIG is not a formal business organization with a board of directors or employees and was, rather, composed only of members who wished to work together, the Defendants and members of the NJPIG were able to exert complete control over the coordinated activities of the NJPIG.</p> <p>Documents evidencing the activities of the NJPIG are included in the attached Manufacturer Interrogatory Appendix 5C.</p>

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Name	Title	Facts Alleged in Support
Midwestern Discussion Group ("MWDG")		<p>The MWDG is an informal group of manufacturers, including Defendants, that met, held conference calls, communicated via emails, and used LinkedIn Group discussion boards to discuss regional specific compliance issues, share information related to DEA enforcement actions against group members, and share interpretations of regulatory requirements. Originally Manufacturer focused, Distributor Defendants were eventually considered for membership due to their close working relationships with the Manufacturers and critical supply chain and strategic business relationships with the same.</p> <p>Because the MWDG is not a formal business organization with a board of directors or employees and was, rather, composed only of members who wished to work together, the Defendants and members of the MWDG were able to exert complete control over the coordinated activities of the MWDG.</p> <p>Documents evidencing the activities of the MWDG are included in the attached Manufacturer Interrogatory Appendix 5D.</p>
Healthcare Distribution Alliance ("HDA")		<p>The HDA is a trade association that has always been operated to advance the agenda of the supply chain entities that form its membership base, including Manufacturers and Defendants. The Distributor and Manufacturer members that controlled the HDA utilized it as a platform to coordinate amongst the activities of its member Defendants but also to coordinate, on their behalf, with other trade associations like PhRMA, GPhA, BIO, and NACDS, as well as informal entities like the PCF (of which the HDA has been a member since 2008).</p> <p>Distributor Defendant members of the HDA hold seats on the board of directors and the executive committee of the HDA, giving them the ability to control and influence the direction of the HDA's work, and the work of its employees, including its executives. The Big Three (AmerisourceBergen,</p>

Name	Title	Facts Alleged in Support
		<p>Cardinal Health, and McKesson) are the three largest members of the HDA and, as a result of their proportionally larger financial support due to the size of their business, were able to exert more control and influence over the HDA than any other member.</p> <p>Pursuant to foregoing, the HDA operated as tool for its members to speak as one voice on issues that affected the supply chain businesses of its members, including manufacturing and distributing. HDA members used this tool to communicate, lobby for, and fund initiatives that furthered the interests of the Opioid Marketing and Supply Chain Enterprises. Beginning in the 1990s, and continuing from 2008 to the present, the HDA began working on Suspicious Order Monitoring issues, including the drafting of policy papers and industry compliance guidelines. In all of HDA's work beginning in the 1990s, the duty to identify, report, and halt suspicious orders – before they became suspicious sales after the fact – has been an established part of the HDA's approach to combatting diversion and suspicious orders. Nevertheless, HDA's members, including Manufacturers and Distributors uniformly ignored their regulatory obligations. In 2008, HDA's Industry Compliance Guidelines were promulgated. The HDA also served as a mouthpiece for it to ask questions to DEA, and articulate messaging that would potentially expose individual members to liability if asked or stated by themselves. On multiple occasions, the HDA worked with PCF, NJPIG, BIO, NACDS, PhRMA, and other groups to advance and support legislation aimed at weakening the DEA and other government agencies working to solve the opioid epidemic.</p> <p>Documents evidencing the activities of the HDA are included in the attached Manufacturer Interrogatory Appendix 5E.</p>

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Name	Title	Facts Alleged in Support
Pharmaceutical Research and Manufacturers of America ("PhRMA")		<p>The PhRMA is a trade association, whose membership includes Defendant Manufacturers. Defendant Manufacturers participation in the organization's various boards and committees provides them control of the actions of the organization. Regular meetings, conference calls, and emails were used to coordinate and share information related to legislative issues related to the use of opioids, quota application issues, suspicious order monitoring requirements, and other legislative and regulatory issues. At various times, PhRMA worked with PCF, NJPIG, BIO, HDA, GPhA, and other groups to advance and support legislation aimed at furthering the use of opioids.</p> <p>Documents evidencing the activities of the PhRMA are included in the attached Manufacturer Interrogatory Appendix 5F.</p>
Generic Pharmaceutical Association (now the Association of Accessible Medicines) ("GPhA")		<p>The Association of Accessible Medicines, formerly the Generics Pharmaceutical Association, is a trade association, whose membership includes Defendant Manufacturers who also manufacture generic prescription drugs. Regular meetings, conference calls, and emails were used to coordinate and share information related to legislative issues related to generic versions of opioids, quota application issues, suspicious order monitoring requirements, and other legislative and regulatory issues. At various times, GPhA worked with HDA, NJPIG, BIO, PCF, PhRMA, and other groups to advance and support legislation aimed at furthering the use of opioids.</p> <p>Documents evidencing the activities of the GPhA are included in the attached Manufacturer Interrogatory Appendix 5G.</p>

Name	Title	Facts Alleged in Support
Biotechnology Innovation Organization ("BIO")		<p>BIO is a trade association of pharmaceutical manufacturers, whose controlling membership includes Defendants. BIO provides a platform for Defendants to fund and coordinate efforts aimed at protecting the industry via opposition to regulatory and legislative threats, as well as litigations against by member companies – including Defendants. Regular meetings, conference calls, and emails provide opportunities for Defendants to collaborate, coordinate their efforts, share information, and direct the organization in furtherance of their misconduct.</p> <p>Documents evidencing the activities of BIO are included in the attached Manufacturer Interrogatory Appendix 5H.</p>
National Association of Chain Drug Stores ("NACDS")		<p>The NACDS is a trade association, whose membership includes Defendant Distributors and Chain Pharmacies. Regular meetings, conference calls, and emails were used to coordinate and share information related to DEA enforcement actions, quota application issues, suspicious order monitoring requirements, and other legislative and regulatory issues. On various occasions, the NACDS worked with HDA, NJPIG, BIO, PCF, PhRMA, and other groups to advance and support legislation aimed at weakening the DEA and other government agencies working to solve the opioid epidemic.</p> <p>Documents evidencing the activities of the NACDS are included in the attached Manufacturer Interrogatory Appendix 5I.</p>
Daniel S. Bennett, MD	Founder/Chairman, Board of Directors, National Pain Foundation	<p>Members of the National Pain Foundation Board of Directors received more than \$950,000.00 from opioid manufacturers, including more than \$250,000.00 from INSYS between 2013–2016; Dr. Bennett received \$170,000.00 from INSYS in that same time period.</p>

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Name	Title	Facts Alleged in Support
Michael Brennan, MD ("Brennan")		MNK paid Brennan to present a speech regarding converting from Oxycodone to EXALGO, an extended-release hydromorphone. Brennan stated Exalgo is meant "for a population of patients who have persistent pain who require a continuous, around-the-clock opioid analgesic for an extended period of time." MNK-T1_0000100452,
Collaborating and Acting Responsibly to Ensure Safety Alliance ("CARES")		<p>Through CARES, MNK promoted the book "Defeat Chronic Pain Now!" (http://www.defeatchronicpainnow.com). The book states:</p> <p>"The bottom line: Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."</p> <p>"Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."</p> <p>"It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."</p> <p>"When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."</p> <p>"Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."</p>
Alan Matsumoto, MD; Martin Angst, MD; Paul Christo, MD; Richard Rauck, MD; Ray Sinatra, MD;		Notable KOLs include but are not limited to these doctor's names, ENDO-CHI_LIT-00547230.

Name	Title	Facts Alleged in Support
Betty Ferrell, MD; Bruce Nicholson, MD		
Charles Argoff, MD		<p>In April 2007, Endo sponsored an article aimed at prescribers, published in Pain Medicine News, titled "Case Challenges in Pain Management: Opioid Therapy for Chronic Pain." Charles E. Argoff, <i>Case Challenges in Pain Management: Opioid Therapy for Chronic Pain</i>, Pain Med. News, http://www.painmedicineneeds.com/download/BtB_Opana_WM.pdf. The article asserted:</p> <p>Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids—the gradual waning of relief at a given dose—and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief. <i>Id.</i> at 1.</p> <p>To help allay these concerns, Endo emphasized the risks of NSAIDs as an alternative to opioids. The article included a case study that focused on the danger of extended use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids.</p>
Gilbert Fanciullo, MD		<p>Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who also served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.</p>

FRONT GROUPS

Endo's Clinical Development and Education division worked closely with medical organizations in the development of educational materials supporting the use of opioids. In a 2000 internal presentation, Endo noted that "JCAHO standards make pain management an imperative." The presentation also listed Endo's role on the JCAHO national committee." ENDO-OPIOID_MDL-02344002. Endo planned to "utilize new JCAHO standards as impetus to establish pain management, as a priority w/PCP's, RPh's, Neuros." *Id.* Particularly in the acute pain space, Endo considered a series of patient educational brochures, focusing on select topics covered by JCAHO and applicable to the company, "e.g. opioid analgesics, pain assessment and acute pain diagnosis." *Id.* It also considered incorporating the "pain as '5th Vital Sign' campaign." *Id.*

In furtherance of its stated goals to "establish Endo as a leader in the field of pain management," Endo identified the "APS guideline project & implementation committee" as an opportunity, along with involvement in three APS regional primary care symposia. *Id.*

A third organization, the National Initiative on Pain Control ("NIPC"), also received support from Endo. A 2001 presentation outlined the relationship between the NIPC and Endo as follows: 1) the NIPC was sponsored by Professional Postgraduate Services ("PPS"), a division of Physicians World/Thomson Healthcare, a for profit corporation 2) the PPS sponsored CME and other educational activities on various pain issues, and 3) many of these activities were supported by unrestricted educational grants from Endo, as disclosed on the educational materials. ENDO-OPIOID_MDL-01928166 at *67. The NIPC itself was also supported by an unrestricted educational grant from Endo. ENDO-OPIOID_MDL-02344215.

The NIPC CME programs focused on issues of pain or opioids generally. In 2002 NIPC coordinated a series of 10 opioid talks, where the NIPC excitedly reported 400 registrants within

the first few days of registration. ENDO-OPIOID_MDL-01761808. Indeed, "Dinner Dialogues", an NIPC program, were a component of Advocacy Development for the Opana brand in development, as identified in the 2002 EN3202 (Opana) marketing plan. END00001522. NIPC reported successful turnout at an Opioid program in Cincinnati held in November 2003. Theresa Leigh, a Cincinnati District Manager thanked her CD&E liaison for facilitating the program, reporting that "[p]rior to the program, Cincinnati Representative, Aymsey Toomer, shared with Dr. Argoff, some of the specific regulatory issues Cincinnati Physicians have been dealing with... Many physicians expressed that they now have an enhanced understanding of the proper prescribing of Opioids while reducing the risk of licensure loss." ENDO-OPIOID_MDL-01761373. Vin Tormo, the CD&E Clinical Liaison responded "Thanks for the feedback Teresa-glad that the program went so well there!!! Glad that your recommendations to the opioid program in Cincinnati paved the way towards, and lessened the fear of appropriately prescribing opioids."

Additionally, Endo maintained a level of involvement in the development of materials presented by NIPC, whether by attending as an "observer" at an educational taskforce developing new curriculum, including study investigators on NIPC faculty, or by weighing in on data to include in the NIPC materials. ENDO-OPIOID_MDL-02261273, ENDO-OPIOID_MDL-01606654, ENDO-OPIOID_MDL-01935133.

Further, there had also concerns about the abuse liability of Percocet, one of Endo's most successful products. ENDO-CHI_LIT-00543481. To prepare the brand team for challenges to Opana, Endo hired crisis management company, Waggener Edstrom, and formed an Issues Management team to develop a crisis response plan for Opana ER. ENDO-CHI_LIT-00543507. Endo's concern was that "Misuse/Abuse risk perception may create negative environment and a PR crisis for OxyM and Endo pain franchise". ENDO-CHI_LIT-00543508. The goals of the crisis response included creating "supportive public policy environment for OxyM and C-II pipeline",

fostering “responsible balance of legitimate patient access and risk management”, and inoculating “against a PR crisis.” *Id.* Internal documents compared this preparation to “Buying insurance”, and rationalized that “While there is no certainty that Endo will face the same kind of crisis in the commercialization of OxyM, we shouldn’t assume that we won’t.” ENDO-CHI_LIT00543498. The Issues Management team recommended that Endo “‘buy insurance’ by investing time and energy now in preparing for a potential crisis so that potential harm may be minimized.” *Id.*

The front groups for the opioid industry and the Defendants herein include but are not limited to:

- Ohio Pain Initiative (“OPI”)
- American Pain Foundation (“APF”)
- American Academy of Pain Medicine (“AAPM”)
- Federation of State Medical Boards (“FSMB”)
- Joint Commission (“JACHO”)
- American Pain Society (“APS”)
- American Society of Pain Educators (“ASPF”)

Pursuant to Federal Rule of Civil Procedure 33(d), Plaintiff identifies the documents concerning front groups listed on Exhibit 5A.

USE AND FUNDING OF KOLS

Endo understood the importance and influence of KOLs to promote the use of opioids generally, and early on began developing influence maps of regional and local KOLs to support EN3202, as reflected in a January 2004 Monthly Business Report. ENDO-CHI_LIT-00552983. This was later integrated into Endo’s strategy of “Building Champions” for Opana ER. ENDO-OPIOID_MDL-00848258. The goal was to “understand who and where the pain medicine thought leaders are”; engage national thought leaders in oxymorphone clinical studies, as advisors, as speakers”; and “utilize national advocates to reach regional and local thought leaders. *Id.*

Cultivating Opana advocates and KOLs to encourage adoption of Opana ER's broader use of opioids to treat chronic pain featured prominently in Endo's pre-launch planning for the Opana franchise. Pre-launch, Endo devised a program to develop "Opana Champions". ENDO00000923. "Champions" would be a part of clinical advisory meetings, marketing advisory boards and promotional breakfast meetings." *Id.*

Periodically, Endo would rank KOLs, referring to it internally as a KOL mapping project. ENDO-OPIOID_MDL-01725812. The project involved determining the KOL's overall impact and assigning them to different categories. Endo examined whether their impact was regional or national in nature, the amount of dispersion across states and the number of people nominating the KOL for their place on the KOL mapping project. ENDO-OPIOID_MDL-01725813. Below are the categories and criteria as identified by Endo in 2007:

Criteria	Concentration	Direct Nominations
National High	Greater than 10 dispersed States	15 or more
National Low	Less than 10 dispersed States	9 or more
Regional High	States closely concentrated	8 or more
Regional low	States closely concentrated	Less than 8
Local High	80% of nominations within 50 miles	5 or more
Local Low		Less than 5

Id.

Overall, the mapping project allowed Endo to identify the Top 200 KOLs for the Opana.

Endo utilized KOLS in a variety of functions supporting Opana. KOL targets were defined as "physicians who are research focused, national level influence, speakers and research publishers in the medical community." ENDO-OPIOID_MDL-00627335 at *38. Internally, these physicians were referred to as KOLs, or Therapeutic Experts ("TE"). ENDO-OPIOID_MDL-00665227 at *34. Members of the Clinical Affairs department, internally referred to as Clinical Affairs Managers ("CAMs"), were responsible for identifying and building "effective working relationships with regional and national TEs in Endo's area of therapeutic interest." ENDO-

CHI_LIT-00237750. In 2008, Endo identified 674 TEs by topic: 187 experts in osteoarthritis, 128 experts in migraine/neuroscience, and 359 Chronic Pain and Moderate-to-Severe-Chronic Pain experts. *Id.* In 2012, Endo reorganized the department and the former CAMs were retitled to Medical Science Liaisons (“MSLs”). ENDO-OR-CID-01299769. However, the MSLs assignments remained the same as before, including communicating with and developing Endo’s KOL relationships. *Id.*

KOLs and TEs participated in marketing panels, pain task forces and speaking engagements. ENDO-CHI_LIT-00547230, ENDO-CHI_LIT-00217549. They also developed materials supportive of the use of long-acting opioids generally. A 2008 Clinical Affairs presentation listed the following examples of development initiatives with Endo’s KOLs: “Portenoy/Fine *Clinical Guide to Opioid Analgesia* handbook”; “Dworkin – IASP closed roundtable/publications on new data/developments in Neuropathic Pain”; “Saper, Silberstein et al – establishment of ICD-9 code for MM”; “Fishbain et al – *Pain Medicine* supplement on oxymorphone”; “Portenoy/Pasternak/Jackson – Opioid rotation roundtable & upcoming publication in *J Pain Symptom Manage*”; and “Fishman & Dahl – national FSMB/state pain initiative project.” ENDO-CHI_LIT-00237750.

Documentation requesting that the doctor be designated as a KOL had to be submitted for review by marketing and medical affairs for approval. ENDO-CHI_LIT-00515301. Exceptions to the Fair Market Value payment restrictions were commonly requested for doctors identified as KOLs. ENDO-CHI_LIT-00217550. These exceptions allowed Endo to pay the KOL in excess of the uniform fee established for other non-KOL healthcare providers.

On May 8, 2012, pursuant to an investigation into the relationship between opioid manufacturers and non-profit health care organizations, the Senate Finance Committee asked Endo to disclose the amount of funding it had paid to prominent KOLs who advocated for the use of

opioids, including, Russell K. Portenoy, M.D., Scott M. Fishman, M.D., Perry G. Fine, M.D., Lynne R. Webster, M.D., Rollin M. Gallagher, M.D., Bill McCarber, M.D., Martin Grabois, M.D., and Myra Christopher, M.D. ENDO-OR-CID-00806002 at *04-05. In Endo's July 6, 2012 response, it disclosed the following total payments: \$73,855.10 to Dr. Portenoy from 1999-2002 for Pain Education, Honorarium and expense reimbursement from 1999-2002; \$8,000 to Dr. Fishman from 2002-2004 for Pain Education; \$36,881.20 to Dr. Fine for pain education, outside contracting services, project consultant from 2002-2007; \$22,500. to Dr. Gallagher for pain education and project consulting from 2001-2005, \$45,193.30 to Dr. McCarberg for pain education, honorarium, expense reimbursement and sales support from 2001-2006; and \$4,000. to Dr. Grabois for pain education in 2004 and 2006. ENDO-OR-CID-00754369 at *07-09. Importantly, Endo reported that the disclosures were for direct payments by Endo and noted the following limitation of its funding disclosure: "Indirect payments to physicians, through third party vendors for events such as conferences, speaker programs, or seminars, may not be identifiable in the SAP system. Accordingly, payments to the individuals listed in request 1(b) by third-party vendors engaged for services by Endo may not be reported, as Endo lacks the systems infrastructure to readily track and report payments made to the individuals through third party vendors." *Id.* at *05.

While direct payments may not have been substantial, Endo regularly employed third parties to facilitate the recruitment and payment of KOLs for various promotional and education programs. For instance, in association with a May 2011 NIPC Dinner Dialogue engagement, the APF forwarded a Faculty Responsibilities Agreement to Dr. Perry Fine in the amount of \$3,000, for his speaking services at the dinner. CHI_001212779. Notably, this payment was not included in the fee disclosure made by Endo to the Senate Finance Committee, as it was within the "indirect" payment category expressly disclaimed by Endo. ENDO-OR-CID-00754369 at *07.

Notable KOL's Endo collaborated with include, but are not limited to: Russell Portenoy, MD; Ray Sinatra, MD; Betty Ferrell, MD; Gilbert Fanciullo, MD; Bruce Nicholson, MD; Charles Argoff, MD; Martin Angst, MD; Paul Christo, MD; Lynn Webster, MD; Richard Rauck, MD; Alan Matsumoto, Md. ENDO-CHI_LIT-00547230. In the Midwest Region, notable KOLs included Dr. Schertzinger (West Chester, OH), Dr. Otten (Columbus, OH), Dr. McGowan, Dr. Hailey, Dr. Peppler, Dr. Scheperle, Dr. Mann (Columbus, OH), and Dr. Sueholtz. ENDO-OPIOID_MDL-00627336 at *7339. In 2013, one presentation boasted "Strong relationships with 1,000 Therapeutic Experts (KOLS)." ENDO-OPIOID_MDL-00665227 at *34.

RISK POSED BY OPIOIDS WERE MINIMIZED IN ENDO'S TRAINING MATERIALS

Training materials utilized by the sales representatives taught specific topics, like low back pain in patients. EPI001554204. These modules gave a comprehensive overview of potential conditions that might necessitate treatment with Opioids, yet they downplayed the risks that opioid medication itself posed. In the low back pain training module, sales representatives learned that "there is a potential for addiction, although this may be less than commonly believed when these medications are used for pain relief." EPI001554204 at *75. It further noted that "[w]hen prescribed properly the use of opioids for chronic pain can be, in some cases, safer than ongoing use of NSAIDS." *Id.*

Sales reps were also coached on concepts like pseudo addiction. A 2006 training manual on the Oxymorphone Risk Management Plan defined pseudo addiction as "an iatrogenic phenomenon in which a patient with undertreated pain is perceived by healthcare professionals to exhibit behaviors similar to those seen in addiction but is not truly addicted." ENDO-CHI_LIT-00053284 at *98. The manual noted that "physicians can differentiate addiction from pseudo addiction by speaking to the patient about his/her pain and increasing the patient's opioid dose to increase pain relief." *Id.* at *99. It offered further reassurance that "[pseudoaddictive behaviors

such as clock watching (counting down the time until the next dose) will resolve when the pain is properly treated. *[AAPM, 2001, 3].*” *Id.*

The manual also downplayed and mischaracterized the risk of physical dependence, comparing physical dependence on opioids to “chronic use of many types of drugs, including many that are not associated with addiction or abuse (such as beta blockers for high blood pressure).” *Id.* Physical dependence was further positioned as an alternative to addiction and explained in the following manner:

[p]hysical dependence can be mistaken for addiction, because in some cases a patient may insist on continued use of the opioid even when pain has resolved, to avoid withdrawal symptoms experience when they try to stop. *[AAPM, 2001, 3].* Withdrawal symptoms can be avoided or managed by carefully-tapering off the dose once pain relief is achieved.

Id. Tolerance to a drug was also offered as an alternative explanation for drug-seeking behavior. Defined as “the body trying to overcome the effects of the drug”, the manual cautioned “[t]olerance can be mistaken for addiction because the patient may ask for increasing doses of the opioid, which can be perceived as ‘drug-seeking behavior’.” *Id.* The section concluded:

the presence of physical dependence and/or tolerance is not sufficient to state that a person is addicted. Patients treated with prolonged opioid therapy do not usually develop addictive disorders, though the actual risk is unknown and likely varies with genetic disposition, among other factors. *[AAPM, 2001, 2].*

Id. at 00.

The manual reassured that addiction was different from tolerance and dependence as,

[a]ddiction is a disorder and not an expected consequence of taking an opioid. By contrast, tolerance and physical dependence are expected physical phenomena associated with opioid use. *[AAPM, 2001, 3]* Tolerance and physical dependence can be mistaken for addiction so the physician must pay close attention to distinguish them from each other.

Id. at 01.

Bates
ENDO-OPIOID MDL-00679355

ENDO-OPIOID_MDL-00679353
ENDO-CHI_LIT-00078382
ENDO-OPIOID_MDL-00680289
ENDO-OPIOID_MDL-00679355
ENDO-OPIOID_MDL-00679355
ENDO-CHI_LIT-00045831
ENDO-OPIOID_MDL-00786258
ENDO-OPIOID_MDL-00679355.
ENDO-OPIOID_MDL-00679353
ENDO-OPIOID_MDL-00684008
ENDO-OPIOID_MDL-00688336
ENDO-OPIOID_MDL-00678060
ENDO-OPIOID_MDL-00680289
ENDO-OPIOID_MDL-00686202 at *03
ENDO-CHI_LIT-00045831
ENDO-OPIOID_MDL-00680289
ENDO-OPIOID_MDL-00680289
ENDO-OPIOID_MDL-00700292
ENDO-OPIOID_MDL-00677219
ENDO-OPIOID_MDL-00684008
ENDO-OPIOID_MDL-00678060
ENDO-OPIOID_MDL-00686202 at *03
ENDO-OPIOID_MDL-00679353
ENDO-OPIOID_MDL-00686202 at *04

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Alan Matsumoto, Md. ENDO-CHI_LIT-00547230. In the Midwest Region, notable KOLs included Dr. Schertzinger (West Chester, OH), Dr. Otten (Columbus, OH), Dr. McGowan, Dr. Hailey, Dr. Pepler, Dr. Scheperle, Dr. Mann (Columbus, OH), and Dr. Sueholtz. ENDO-OPIOID_MDL-00627336 at *7339. In 2013, one presentation boasted “Strong relationships with 1,000 Therapeutic Experts (KOLS).” ENDO-OPIOID_MDL-00665227 at *34.

On February 15, 2013, Endo submitted a labeling supplement proposing additions to the label including “pre-and postmarketing data from in vitro and in vivo abuse potential studies to the DRUG ABUSE AND DEPENDENCE section of the Package Insert.” ENDO-OR-CID-01174358. On May 10, 2013, the FDA denied the application and highlighted the following concerns about the formulation:

no pharmacokinetic studies measuring serum concentrations following nasal administration or assessing the ability to insufflate have been conducted. Additionally, no human abuse liability studies examining abuse by the nasal route of administration have been conducted. The ease with which the product can be manipulated, and the ease with which oxymorphone can be extracted from the manipulated product, are not consistent with a formulation that would provide a reduction in oral, intranasal or intravenous abuse of Opana ER.

Id. at *58-59.

The FDA also cited concerns with the post marketing data Endo submitted in support of the label change. The FDA found,

[t]he postmarketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse of Opana ER due to:

- the short period of time represented
- the overlap of prescriptions for both the original formulation of OPANA ER and reformulated OPANA ER during the first quarter of the reporting period
- the continued availability of original OPANA ER throughout the reporting period

- the possible misclassification of the original and reformulated products based on the similar appearance of the two products.

ENDO-OR-CID-01174359.

Use of KOLs and front groups/professional organizations:

- a) MNK-T1_0000111160
- b) MNK-T1_0000258075, Value proposition research reports
- c) MNK-T1_0000225603-604
- d) MNK-T1_0000222031
- e) MNK-T1-00126200, MNK Power Point presentation re: marketing MNK-795 referencing C.A.R.E.S. Alliance and Pain Care Forum
- f) MNK-T1_0000100452, script for speech "Exalgo On-Demand" by Michael Brennan
- g) MNK-T1_0000225603-604, e-mail re repositioning C.A.R.E.S. Alliance
- h) MNK-T1_0000206953, re "Global Medical Affairs Nursing Advisory Board"
- i) MNK-T1_0000232868, "Professional Alliances: Needs Justification" presentation.

Use of speakers' bureau:

- a) MNK-T1_0000539986, Field Sales Expense Review FY13 & FY14

PAIN IS "UNDERTREATED"

An article written by the APF demonstrates that surveys suggesting that pain is "undertreated" were produced by the pharmaceutical companies – and for the purpose of gaining media placement and influencing consumer attitudes. JAN-MS-02325533.



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**Review of American Pain Surveys
Designed to Gain Media Placement and/or
Influence Consumer Attitudes**

1994-Present
Prepared by the American Pain Foundation
May 2002

Summary

The following is a review of nine US pain surveys, arranged by date, that were conducted over the last seven years. All but one—*Pain in America: A Survey of American Attitudes Toward Pain*, sponsored by the Mayday Fund—were commissioned by pharmaceutical companies and developed by public relations agencies for the purpose of influencing consumer attitudes and promoting a particular product or a class of drugs. Several of these surveys were done in collaboration with nonprofit organizations. Some of the surveys had a particular focus (e.g., effect of pain on the elderly, pain and work, pain and gender differences, etc.).

The APF researched the all the surveys conducted by the industry and determined them to be biased. JAN-MS-02325533 at -34.

To date, all but one (the Mayday survey) of the general, non-disease specific, national pain surveys were commissioned by individual pharmaceutical companies for the purpose of creating awareness about pain and (indirectly) promoting a product or class of drugs. The most commonly used method to accomplish this was to craft questions designed to demonstrate the dangers, or lack of effectiveness, of other types of drugs or delivery systems. . . . None of the surveys were initiated by nonprofit pain advocacy or professional organizations or epidemiological research organizations. Nonprofit organizations were often involved to lend credibility to the studies and increase likelihood of media coverage. Reputable polling firms (Louis Harris, Roper Starch, etc.) were employed to conduct surveys to give credibility to them.

JAN-MS-02325533. The APF report concludes that there is a need for a large-scale, unbiased pain survey, conducted by epidemiologists. JAN-MS-02325533 at -35. "Everyone working to improve pain management . . . needs reliable and current statistical data to inform and guide their work. As

the old adage goes, *you cannot manage what you cannot measure.*" JAN-MS-02325533.

The studies that APF researched include the following:

1. 1995 *National Pain Survey* by McNeil Pharmaceutical: "The key finding was that the majority of patients were reluctant to take certain types of drugs because of fears about side effects such as gastrointestinal bleeding and potential for addiction." *Id.* at -36. The survey coincided with the 1995 FDA approval and launch of Ultram (a version of which is co-promoted by Purdue).
2. 1996 *Pain and Absenteeism in the Workplace* by Ortho McNeil Pharmaceutical: "The study was designed to promote Ultram . . ." Its key finding was that untreated pain was a detriment to business. *Id.* at -36.
3. 1997 *Pain and the Older Americans Survey* by Ortho McNeil Pharmaceutical: Key finding was that a large number of older Americans take too many NSAIDS and end up with gastrointestinal problems. The study targeted potential users of Ultram. *Id.* at -37.
4. *The 1999 National Pain Survey* by Ortho McNeil Pharmaceutical: The survey is a follow-up on the 1994 survey that examined "the analgesic dilemma," not included in this APF report, which looked at patient fears about side-effects, addiction, and prescribing practices. *Id.* at -40. Among key findings: 9 in 10 physicians were concerned about opioid side effects, including addiction. *Id.* An email within Janssen on October 29, 1999 regarding KOL interviews is potentially related.
5. 2000 *Pain in America: A Research Report* by Merck & Company: Among the key findings, nine in ten Americans suffer from regular pain. *Id.* at -41.
6. 2000 *Chronic Pain in America: Roadblocks to Relief* by Janssen Pharmaceutica, the American Pain Society, and the American Academy of Pain Medicine: This survey was conducted between November 1998 and January 1999. Its stated purpose was to heighten awareness among consumers and the medical community on the issue of chronic pain and the need to treat it aggressively. *Id.* at -43.
7. 2000 *A Survey of Pain in America* by Purdue Pharma (Partners Against Pain): The survey was designed specifically to promote OxyContin. *Id.* at -45.
8. 2001 *Gender Attitudes Toward Chronic Pain* by Purdue Pharma (Partners Against Pain) and the National Women's Health Resource Association. *Id.* at -46.
9. 2002 *Pain in Maryland* by Medtronic, Abbott, the American Pain Foundation and the Maryland Pain Initiative. *Id.* at -47.

Purdue internally recognized that later surveys by Janssen were "clever marketing."

PLPC009000079874.

Shortly before the above report was published, the executive director of the APF and Dr. Richard Sackler of Purdue had a direct relationship. On February 11, 1999, the executive director of the APF, Jim Guest, emailed Dr. Richard Sackler, thanking him for a \$250,000 contribution and alerting him to impending legislation. PPLPC026000000291. Guest and Sackler discussed that Guest approach Janssen to leverage a similar grant. *Id.* Guest followed up on it, because the APF approached Janssen asking for \$250,000. JAN-MS-01052077. *See also* PPLCP018000004292 (email with evidence of funding from Ortho-Biotech, APS, Knoll, and Endo).

By August 5, 2000 Purdue expected return on that financial support for APF. Robin Hogen emailed Haddox about APF executive director Jim Guest, saying “[i]f they want our bucks (and they honestly cannot survive without industry support) they are going to have to learn to live with ‘industry’ reps on their board. I don’t think they can expect huge grants without some say in governance.” PPLPC025000012558. Guest discusses with Sackler that the APF does not want industry connections on the board because it wants to avoid the appearance of impropriety – while keeping Sackler informed about the APF’s every move.

Guest’s email also referenced the Pain Relief Promotion Act, stating that the Pain Care Coalition (APS, AAPM, ASA) specifically asked for the declaration that this is the “Decade of Pain Control and Research.” PPLPC025000012558. June Dahl of the Pain & Policy Studies Group was also involved. PPLPC025000012558.

Pre-2001 Guidelines

Prior to 1994, physicians treated cancer pain according to the World Health Organization’s (“WHO”) three-step analgesic ladder. *See* PKY183222319 at -22. Step 1 of the WHO ladder represented treatment of mild pain with aspirin, acetaminophen, and NSAIDS. PKY183222319. Step 2 of the WHO ladder represented moderate pain, treated with “weak” opioids like codeine,

oxycodone, and hydrocodone. PKY183222319. Step 3 represented severe pain, usually treated by either fentanyl or morphine. PKY183222319.

In 1994, the Agency for Health Care Policy and Research ("AHCPR") adopted Clinical Practice Guidelines for the Treatment of Cancer Pain. The AHCPR is a branch of the Department of Health and Human Services ("HHS").

Purdue recognized that guidelines could be used to sell MS Contin and partnered with AHCPR to distribute the guidelines. PDD1706039146. Indeed, Purdue timed the launch of its Partners Against Pain program to coincide with the release of the AHCPR guidelines. PKY180628795.

March 7, 1994

F-D-C REPORTS — "The Pink Sheet"

- 9 -

PURDUE FREDERICK "PARTNERS AGAINST PAIN" PROGRAM LAUNCHED TO COINCIDE WITH AHCPR GUIDELINES; PURDUE FREDERICK SALES FORCE WILL DISTRIBUTE GOVERNMENT GUIDES

Purdue Frederick is incorporating clinical practice guidelines from the Agency for Health Care Policy & Research into a promotional/patient education campaign for pain control.

PKY180628795. In a Quarterly Report about MS Contin from Michael Friedman to the Sacklers,

Mr. Friedman recorded:

These guidelines are a selling tool that we can use. . . . In anticipation of the publication of the AHCPR guidelines we trained influential physicians on how to deal with media and enlisted their support for our public relations campaign. Two days before the guidelines were published our press-kit was sent to approximately 600 reporters and our video news release and sound tape was sent to over 150 TV and radio stations . . . We have numerous reports of our product being displayed in a favorable light during press coverage of the AHCPR guidelines.

Id. PDD1706039146 at -47.

The Pink Sheets, a daily business publication, reported that "[t]he Purdue Frederick adoption of the AHCPR guidelines into its program is one of the most direct uses of a recommendation from that agency by a pharmaceutical maker." PKY180628795. The University

of Wisconsin, home to the soon-to-be-formed Pain & Policy Studies Group, was also involved in creation of the guidelines. As part of the AHCPR guideline distribution, one of AHCPR's cancer pain board members, Charles Cleeland, PhD, of the University of Wisconsin Medical School, authored an article about the undertreatment of cancer pain, published in The New England Journal of Medicine. PKY180628795. Also involved in the Purdue program launch were two cancer specialists from the Fox Chase Cancer Center in Pennsylvania, both of whom were consultants to the AHCPR in creating the guidelines: Michael Levy, Md/PhD, and Pamela Kedziera, RN. PKY180628795.

Purdue recognized that the AHCPR guidelines were favorable to OxyContin in that they 1) "reinforce [the] principle of tailoring pain medications to the individual patient by titrating upward before switching, 2) "using adjuvant agents," and 3) "treating specific types of pain with individual agents," as opposed to mixing, for example, opioids and NSAIDs. PKY180287212 at -20. "The dosing flexibility offered by OxyContin is consistent with these guidelines as a Step 3 agent." PKY180287212

Purdue's intent, however, was to position OxyContin in Step 2 of the WHO ladder, for more moderate, non-cancer pain, and to push fentanyl to the most extreme of Step 3. *Id.* at -22, 25-29. Purdue intended to do this by "engineering" successful trials. *Id.* Purdue also planned a play, direct mailers, and certification programs for oncology nurses (through a grant to ASPMN), and a media roundtable (using representatives of relevant associations for "third-party credibility"), and press information packages. PKY180287212.

By 1995, Purdue was watching the APS guideline process. PDD1501803068. An unidentified Purdue custodian printed and highlighted a copy of the 1995 APS Consensus Statement, "Quality Improvement Guidelines for the Improvement of Acute Pain and Cancer Pain." PDD1501803068. The highlighted portions read:

By making the magnitude of the problem [of undertreated pain] apparent and committing the institution to change, pain treatment QI programs can provide a foundation for a multifaceted approach that includes education of clinicians and patients, design of informational tools to minimize errors in prescribing, and improve coordination of the process of assessing and treating pain. . . . The targeted outcome was that each patient would receive timely and optimal doses of analgesic drugs.

PDD1501803068 at -68-70. The article also notes that the draft guidelines were circulated to the full membership for comment. PDD1501803068 at -70. The drafting committee was composed of the following members: Mitchell B. Max, MD (National Institute of Health/National Institute of Dental Research); Marilee Donovan, Ph.D., RN (Kaiser Sunnyside Medical Center); Christine A. Miaskowski, PhD, RN (University of California); Sandra E. Ward, PhD, RN (University of Wisconsin); Debra Gordon, MSN (University of Wisconsin); Marilyn Bookbinder, PhD, RN (Memorial Sloan-Kettering Cancer Center); Charles S. Cleeland, PhD (University of Wisconsin); Nessa Coyle, RN, MS (Memorial Sloan-Kettering Cancer Center); Margaret Kiss, MS, RN (Memorial Sloan-Kettering); Nora Janjan, MD (University of Texas M.D. Anderson Cancer Center); W. Thomas Edwards, PhD, MD (Harborview Medical Center). Contributions from the following people were also noted: Margo McCaffery, RN, MS; Carol Howe, MSN; Susan Hagan, BSN, MS; Mary Layman Goldstein, RN, MS; Susan Derby, RN, MS; Mary Born, RN, MS; Betty Ferrell, PhD, RN; Jan Frandsen, RN, MS; Daniel B. Carr, MD; Sri Vasudevan, MD; Russell Portenoy, MD. PDD1501803068 at -74.

By May of 1998, the American Geriatric Society published new guidelines for treating pain in the elderly, in which Janssen was involved. JAN-MS-00270843. An email was sent around Janssen, specifically the Ortho-McNeil division (then responsible for Ultram), inquiring as to whether the company had any influence over the AGS guidelines. JAN-MS-00270843. The answer was that Ortho-McNeil did not but that “[i]t was all driven by the Tylenol brand.” JAN-MS-00270843. “[W]e were invited to join the MCP folks at a final meeting at AGS . . . I’d inquired

as to whether we could somehow get ULTRAM also considered for inclusion in these g'lines, and unfortunately was told that their scientific advisors had already signed off on them (the ULTRAM brand was aware of this)." JAN-MS-00270843. Because of coverage on NSAIDS and undertreatment of pain, the Ortho-McNeil strategy going forward was get media to discuss effective treatments for chronic pain (which would presumably include ULTRAM and other opioids). JAN-MS-00270843.

Purdue and Ortho McNeil were at the time meeting to discuss Ultram. PPLPC018000002278. Friedman's notes from an April 1997 meeting reveal that Ortho McNeil sought to position Ultram as an alternative to "dangerous" NSAIDS. The two sides discuss broader pain policy, but primarily with respect to scheduling and the FDA, not guidelines.

From August 23-25, 1998, Purdue was looking at pain guidelines. See the PPSG website of various state guidelines and articles. PKY183028750, PKY183028698, PKY183052486.

The 2001 JCAHO Guidelines & Model State Guidelines

The WHO, AHCPR, and APS guidelines "had not worked," meaning they were not being uniformly implemented by healthcare providers. David Baker, MD, MPH, *The Joint Commission's Pain Standards: Origins & Evolution*, The Joint Commission (May 5, 2017), https://www.jointcommission.org/assets/1/6/Pain_Std_History_Web_Version_05122017.pdf. Under those guidelines: "Physicians were 'rarely held accountable' for inadequate pain control, and they had not implemented systems to address the problem." *Id.*

Purdue representatives sought creative ways to enforce older guidelines. They quizzed doctors on the AHCPR guidelines, "establishing the federal guidelines as the *Standards of Care* for cancer pain management" and making doctors members of "The Pain Team." PKY180242433. Purdue representatives would then "transform the 'Big Picture' to a personal level" by "showing

the Federal Guidelines information is being incorporated into the survey evaluation process for JCAHO (Joint Commission on the Accreditation of Healthcare organizations).” The implication of the “personal,” is that the doctor could get in trouble for undertreating pain. “Talking about their personal role in patients care and the practical application of the Federal Guidelines recommendations usually leads to a discussion of a patient they currently have under their care. At this point the Purdue Frederick sales representative is transformed into a Pain Management Consultant.” *Id.*

On November 12, 1999, Janssen sent a bulletin out to its sales force about a report in the *British Medical Journal* of a doctor being disciplined for undertreating pain. JAN-MS-02728546. “One of the issues that is driving the rapid expansion of the pain market is the changing attitude towards the treatment of chronic, severe pain.” JAN-MS-02728546.

The Robert Wood Johnson Foundation (“RWJF”) funded the Joint Commission to develop pain standards in collaboration with the University of Wisconsin-Madison School of Medicine (Pain & Policy Studies Group) “and experts from around the country.” JAN-MS-02728546. Those standards would go into effect in 2001. The Robert Wood Johnson Foundation also funded creation and dissemination of the Model State Guidelines through the Federation of State Medical Boards. PDD1706042217. It also funded the Pain & Policy Studies Group. PDD180550457. Dr. Payne’s resume shows substantial overlap between RWJF and Janssen advisory boards. JAN-MS-00402671.

The RWJF currently owns nearly \$2 billion in J&J common stock, and the organization has been funded from its inception (at least in part) from that stock grant.³

³ <https://www.rwjf.org/content/dam/files/rwjf-web-files/Financials/FY2017-RobertWoodJohnsonFdn-FS.pdf>

Around July 1997, an unidentified Purdue employee wrote an internal memo regarding the need for consensus guidelines on the treatment of non-malignant pain. PKY181320029; PKY183033731. The memo references a Janssen study in Business and Health as demonstrating undertreatment of pain and suggests creating the guidelines to distribute to Purdue's "core audience involved in non-malignant pain management." PKY183033731.

By 1998, Purdue had thought leaders teaching CMEs on "Defining New Standards of Care" through the University of Wisconsin Medical School (Pain & Policy Studies Group), which was currently working on the JCAHO standards. PKY180947825. At least one of the thought leaders, Cohen, disclosed that he received funding from both Janssen and Purdue. PKY180947825.

By late August of 1998, Purdue drafted out its plan to influence pain treatment guidelines disseminated by state medical boards – and recorded that plan in a memo. See PKY183033795. An early version of the memo records that "some physicians have stated that not relieving pain optimally is tantamount to moral and legal malpractice." PKY183028056 at -56. The memo focuses on barriers to using opioids in non-cancer pain, identifying those barriers as 1) burdensome state laws and regulations, 2) inadequate training of providers, 3) provider concerns of addiction and investigation, 4) societal attitudes, and poor coordination among policy makers, consumer groups, purchasers, and health care providers. PKY183028056 at -56-57. "Toward this end, the Federation of State Medical Boards has drafted model guidelines for prescribers, which the federation hopes will be adopted universally. Pain policy analysts we spoke with argue that a non-legislative approach to affecting change (*i.e.*, adopting practice guidelines) is better than a legislative approach because guidelines are easily modified as the practice of pain management changes." PKY183028056 at -58.

The early version of the memo discusses "opportunities" and cites "independent research organizations" who study pain and policy: the Midwest Bioethics Institute and the Pain & Policy

Studies Group. *Id.* The memo states that the groups' large research projects have been funded largely through the Robert Wood Johnson Foundation; it gives one example of an \$11.25M program, Community-State Partnerships to Improve End-of-Life Care, though which grant applicants are advised to include in their proposals plans to "develop and disseminate guidelines that promote effective pain management." *Id.* 47 of 50 states submitted programs. PKY183033795 at -98.

The Purdue guidelines memo eventually became a formal Partners Against Pain booklet titled "Fostering Change in the Pain Management Environment," Purdue worked on the project through Fleishman-Hillard, Inc., a public relations firm. PKY183028056. Program objectives: "Strategically foster public policy changes in the use of opioids for pain management. Impact the prescribing environment in which opioids are used for responsible pain management. Position Purdue Pharma with key stakeholders in a manner that will be helpful to future product launches." PKY183033795 at -99. The memo determines that the most impact can be had on the state level, and it identifies specific states to start with. *Id.* at -03.

"This plan will support existing state efforts, such as The Robert Wood Johnson Foundation's Community-State Partnership Program, which will put tremendous dollars and influence behind reworking pain management guidelines and legislation. Our preliminary assessment is that this program presents opportunities for alliance building for Purdue Pharma." *Id.* Purdue then produced the brochure titled "The Seven Myths of Pain Management" that it disseminated as an educational piece for "decision-makers, opinion shapers and consumers." *Id.* at 00.

Purdue and Janssen had tactical meeting around October 13, 1998, bringing leadership and sales representatives together to discuss Ultram SR business plans. JAN-MS-00270848. Purdue and Janssen met again in November 10, 1998 to discuss abuse liability for Ultram SR in relation

to their NDA submission to the FDA. JAN-MS-01051749. The companies continued working together at least through January of 1999 to address clinical trial issues. JAN-MS-01051770.

Around the same time, a PowerPoint presented by the R.W. Johnson Pharmaceutical Research Institute, J&J's umbrella research subsidiary advocates for the development of pain treatment guidelines across the spectrum of painful conditions, as well as pain management conference and a coordinated education program for physicians, insurers, and patient advocacy groups. JAN-MS-01003804; *see also* JAN-MS-02759375, JAN-MS-00456512, JAN-MS-02727945. Janssen believed guidelines were "underutilized." JAN-MS-02727943. It is also around this time that Janssen begins considering combining J&J's pain franchise, currently split between Janssen, Ortho-McNeil, and Pri-Cara. JAN-MS-02727943.

On December 1, 1998, Janssen met with the AGS board of directors to discuss updating the new AGS guidelines. JAN-MS-00270846.

In December 1998, Purdue was already anticipating using the JCAHO guidelines to sell – before the guidelines were published, including a JCAHO "compliance kit" on making pain management appropriate for all patients, not just the dying. PKY18122672.

By February of 1999, Purdue sought to partner with the VA and APS on the "Pain: The 5th Vital Sign" campaign. PKY183036326. Purdue planned to "[e]xtend base of support to states via VA network, state medical boards, or managed care organizations." PKY183036326. at -26. At the time, Purdue already envisioned a consensus statement from APS and AAPM as part of the plan, intending to pass out the guidelines and consensus statements at CME programs. PKY183036326. at -28. "Foster changes in pain management through educational seminars directed at physicians and thought leaders . . ." PKY183036326. at -27.

Initially, Purdue intended to target ten states, those with the best business development opportunities. PKY183036326. at -26. This was accomplished through Fleishman-Hillard and

Lyons Lavey Nickel Swift, Inc. *Id.* On August 11, 1999, an internal email asked how to get “mileage” from a New York Times article about pain killers and new guidelines. PPLPC012000005648. The response was that Purdue should put together programs based on its experience in California, Nevada, and Ohio. PPLPC012000005648. “If we can get the governing board’s message out, it can only help us sell more.” PPLPC012000005648. By March of 2001, a Janssen consultant, Discovery International, recommends targeting the state medical boards to expand the FSMB 1998 Model Guidelines, as well as breaking down the JCAHO guidelines to make them more easily accessible to doctors. JAN-MS-003131999 at -01.

By 1999 Purdue sent an employee to speak with “key JCAHO players” about Purdue’s interests. PDD1701879922.

In June 2000, evidence links Purdue and RWJF. PPLPC029000018652. The parties intended to meet to discuss how to partner with RWJF’s “Last Acts” campaign. PPLPC029000018652. Michael Friedman and Robert Reder attended the meeting, and potentially Haddox. PPLPC029000018652.

In September 2000 a Purdue publication titled “Preparing for JCAHO: Implications for the Case Manager” stated: “In 2001, for the first time, all JCAHO-accredited institutions and organizations will be expected to demonstrate their ability to assess and manage pain in all patients, not just in the final days of life, but across the continuum of care.” PDD8801316960. JCAHO education materials became standard for Janssen representatives by November of the same year. JAN-MS-02327808.

Then, in November of 2000, several companies cooperated with the NPC and JCAHO to disseminate the new guidelines. JAN-MS-00654711; JAN-MS-00654707-11. On November 28, 2000, Jeann Gillespie from the NPC emailed employees from Janssen, Knoll, AstraZeneca, Abbott, Pfizer, BMS, Merck, and, curiously, Monsanto to inform them that the JCAHO “pain

management project” is moving forward. JAN-MS-00654711. Through the project, NPC and JCAHO intended to produce pain management monographs with a prestigious editorial advisory board; Gillespie asked for recommendations, suggestions, and comments. JAN-MS-00654711. She also promised to send out invoices and logistics for the companies’ financial commitments. JAN-MS-00654711.

On December 8, 2000, Bruce Moskowitz sent Gary Vorsanger an email about the NPC JCAHO project, attaching an update and notes from an October 19 call. JAN-MS-00654707. JAN-MS-00654709. The parties discussed educational monographs on pain treatment to “raise awareness and identify gaps.” JAN-MS-00654709. “This approach is high level and non-drug specific, which is essential for collaboration.” JAN-MS-00654709. An expert panel and monographs were proposed, with the panel to include “leaders and stakeholders that have experience in measuring and improving compliance with pain management guidelines.” JAN-MS-00654710. In the meeting, Dave Kerr from Knoll discussed sponsoring two pain-management summits with Purdue. JAN-MS-00654709. A \$50,000 investment was requested from each company. JAN-MS-00654709.

The Defendants had input on the monographs. On April 1, 2001, Moskowitz sent a draft of the Pain Management Monograph from the NPC to an employee to “determine whether any treatment guidelines that include OxyContin and Duragesic are appropriately addressed.” JAN-MS-00655132. This is not the only time that Janssen would look out for the interest of Schedule II drugs as a class, not just Duragesic, as further described below. The final manuscript is attached to JAN-MS-02336600, and Vorsanger says he thinks it will be useful for marketing. Janssen intended to give it to “customers who ask about pain management.” JAN-MS-02336678. Janssen, and all of the involved companies, received 5,000 copies of the monographs. JAN-MS-02109392.

Ohio reps were taking the “5th Vital Sign” (JCAHO guidelines) message to doctors, saying, “It cannot be ignored.” JAN-MS-00306718. Telling reps to give doctors a pain contract if they are concerned about treating with opioids, and to do speakers programs to address substance abuse.

In 2002, Purdue internally discussed Janssen’s product growth, saying that growth “require[s] unique tactics such as JACHO and similar programs.” PLPC009000079874.

In April of 2016, JCAHO would release a statement on “misconceptions” surrounding the 2001 JCAHO guidelines. https://www.jointcommission.org/joint_commission_statement_on_pain_management/. Those misconceptions include:

1. The Joint Commission endorses pain as a vital sign.
2. The Joint Commission requires pain assessment for all patients.
3. The Joint Commission requires that pain be treated until the pain score reaches zero.
4. The Joint Commission pain standards caused a sharp rise in opioid prescriptions.

The University of Wisconsin’s Pain & Policy Studies Group

The Pain and Policy Studies Group, out of the University of Wisconsin, played an important role in the 2001 JCAHO guidelines. The primary individuals associated with the group are June Dahl and David Joranson.

A Milwaukee newspaper interviewed Dahl and summarized the PPSG and market expansion story:

The analytical Dahl — who, at 84, is among the oldest active Wisconsin professors — reflects, then says candidly: “It appears that the promotion of better pain management has led to more liberalization of the prescribing of opioids, which has led to an increase in the availability of the drugs, which has led to some people abusing them, and then, when they can’t get pills, to heroin as criminals promoted it.”

http://www.gmtoday.com/news/local_stories/2014/heroin-special/09102014-uw-madison-researchers-played-role-in-increasing-opioid-use.asp. Dahl told the paper that pain policy “needed

a stick,” so “Dahl (with Robert Wood Johnson funding) began encouraging the Joint Commission, which accredits most American hospitals and doctors’ offices, to adopt new pain assessment standards.” *Id.* Once JCAHO adopted the new standards, doctors and hospitals would be accountable for undertreating pain.

The Robert Wood Johnson Foundation funded the Pain & Policy Studies Group. PDD180550457; WIS_PPSG_002971; WIS_PPSG_010253; WIS_PPSG_011735. Janssen gave it startup money. PPSG members, RWJF, and Purdue communicated closely. WIS_PPSG_000511; PPLPC029000018652. Robert Wood Johnson Foundation also funded creation and dissemination of the Model State Guidelines through the Federation of State Medical Boards. PDD1706042217. Dahl was also on Janssen’s NPEC board.

Beginning in 1997, Purdue and Janssen (through Ortho-McNeil) co-promoted Ultram SR. PPLPC018000002278; PKY181968431, JAN-MS-00456519. A letter from a Purdue employee to Michael Friedman recounts how Ortho McNeil worked with the FDA to ensure that Ultram was kept at a lower schedule level – and created what was perhaps the first industry/government addiction monitoring program. PKY181424209. The letter states that Ortho McNeil had Dr. Sydney Schnoll convene a group of addiction specialists at McNeil corporate headquarters to discuss how to persuade the FDA to consider a lower schedule. Ultimately they put in place a “program where the responsibility for monitoring potential abuse problems would be shared by both government and the manufacturing organization.” PKY181424209. “The work of Dr. Schnoll’s group ultimately contributed to the non-scheduled status of Ultram.” PKY181424209. “Even though Ultram in long term use anecdotally is known to cause dependence and in some causes addiction problems, when these troubles do occur McNeil is usually the first to know about them and is able to take appropriate action to resolve the problem.” PKY181424209. The Purdue employee says this is made possible through a database that monitors prescriptions.

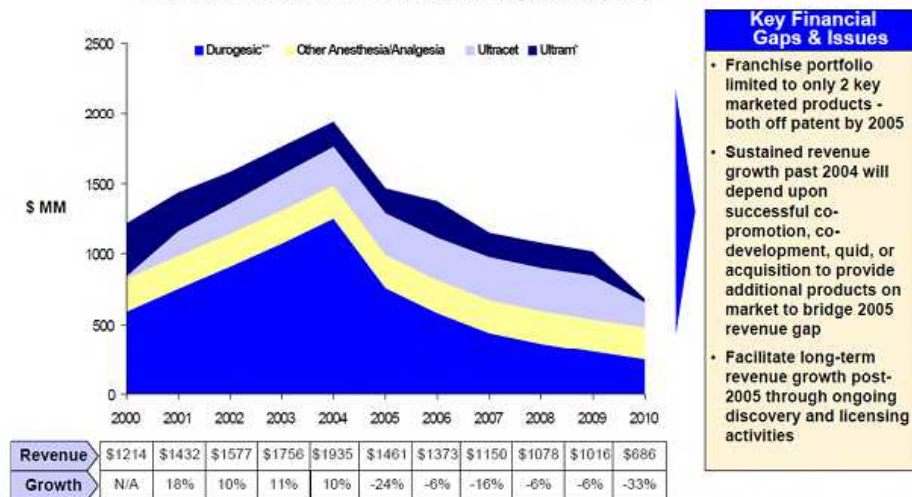
This is corroborated by Friedman's notes from the April 1997 Ultram meeting between Purdue and Ortho McNeil. PPLPC018000002278.

By May of 2000, Janssen was aware that it had a "gap problem" for the year 2005. As of that time, Janssen through Ultram and Duragesic controlled 11% of the pain and inflammation market, a share valued at \$1.3 billion to the company. JAN-MS-00456087. But without new drugs or expansion of the product base, that share drops to \$686 million by 2010, with a steep decline at 2005 before new products could be introduced. JAN-MS-00456087 at 25.

PAIN AND INFLAMMATION FRANCHISE - Internal Gap / Opportunity Analysis P - SM

Financial Projections and Growth

Franchise 10-Year Revenue & Growth Projections (WW)



Source: Portfolio forecasts. *Ultram includes Ultram & Ultram SR. **Duragesic includes Duragesic, Duragesic 12.5, & Duragesic Matrix
JJPG Confidential

Pain & Inflammation
Franchise Plan 25

Janssen knew that opioid use is increasing because of improved perception of health care policy stakeholders, specifically the WHO and NIH. JAN-MS-00456087. "Demand exists for products that offer the efficacy of opioids but do not have the associated side effects or addiction potential." JAN-MS-00456087. Janssen apparently intended to invest up to \$80M in Ultracet and

Duragesic DTC marketing, recognizing the potential in non-cancer pain and “under-treated groups.” JAN-MS-00456087. At this time, the Janssen US sales force viewed Duragesic as second detail, and there was no Janssen primary sales force for analgesia in US. JAN-MS-00456087.

Thus, Janssen began looking for a co-development project by year end 2000. “Increased industry reliance on partnerships poses both opportunities and competitive threats.” JAN-MS-00456087. The top-line recommendation: co-promote and co-develop to pursue 2005 revenue potential. JAN-MS-00456087.

At the same time, Purdue’s sales of OxyContin were just beginning to pull ahead of Janssen’s sales of Duragesic. JAN-MS-00615319. By 1997, Purdue was anticipating a generic of MS Contin, and “one of the primary objectives is to capture patients who would have been started on MS Contin to OxyContin, as quickly as possible.” PKY183222319 at -25. Janssen has been targeting the moderate to moderately-severe market for the past two to three years but making slow progress. PKY183222319. Janssen spent over \$1M in 1996, through August, advertising in Journals to target internists and PCPs (as opposed to pain specialists).

In April of 1994, Purdue commissioned Strategic and Tactical Recommendations for OxyContin’s 1996 launch; at that time, the recommendation was to position OxyContin to treat cancer pain. PKY180287212 at -13. But from the outset, Purdue intended to expand into non-cancer pain. PKY180287212 at -35. However, it appears from the Strategic and Tactical Recommendations that such an expansion would have to occur *after* the launch in cancer pain. PKY180287212 at -35. By 1998, the OxyContin budget included a plan to “enhance the acceptance of opioids for non-cancer pain.” PKY180233846 at -60. The plan was to “attach an emotional aspect to non-cancer pain so physicians treat it more seriously and aggressively.

PKY180233846. “The positive use of opioids, and OxyContin Tablets in particular, will be emphasized.” PKY180233846 at -63.

On March 20, 2000, Janssen’s Global Commercial Team (“GCT”) met to discuss objectives. JAN-MS-00478443. Among them was moving the position of Duragesic from Step 3 (“mostly cancer pain”) of the WHO pain ladder to Step 2 (“opioids-non opioids, for chronic pain overall in opioid naïve patients”) of the pain ladder. JAN-MS-00478443. The GCT expressed intent to build a “spine” for the overall commercial development, publication, and communication strategy, saying “[w]e must be the champion to insure maximal support at the OC level to grow Duragesic above the \$1 billion level before 2003.” JAN-MS-00478443. In furtherance of the scheme, Defendants convened a panel of experts in Rome to gather information for marketing Duragesic. JAN-MS-00478453. Noted was consensus that “high quality evidence to support the use of DUROGESIC in chronic non-cancer pain is required, particularly from long term studies.” JAN-MS-00478453 at 2, 4, 6. Also at JAN-MS-00478471.

Later, a February 16, 2000 email confirms a March 17, 2000, four-hour meeting between Janssen and Purdue. JAN-MS-0246903. On the agenda are Janssen’s current pain audience, Ortho-McNeil’s current pain audience, Purdue analysis, co-promotion options, and next steps. JAN-MS-0246903.

This meeting was discussed at the Janssen Global Commercial Team level because March 20, 2000 Janssen GCT meeting notes says, “VC to deliver extensive buprenorphine competitive assessment to next GCT meeting (sales forces, claims etc.) Other product mentioned: OxyContin and Palladone.” JAN-MS-00478443 at -45.

By May 2000, Janssen had created plans to present to Purdue, including a plan to co-promote OxyContin. JAN-MS-01052181. “Project Objective/Rationale: Build a partnership between Purdue Pharma LP and J&J that leverages each partner’s assets and capabilities to create

a Pan Management Franchise that is significantly larger and more profitable than that which the partners could build on their own.” JAN-MS-01052181.

A Powerful Combination

J&J

- Sales/Marketing
- Tylenol & Motrin
- Duragesic
- Ultram/Ultram SR
- Ultracet
- Intellectual property
- R&D pipeline and capabilities

Purdue

- Sales/Marketing
 - Oxycontin
 - MS Contin
 - Ultram SR
 - Palladone
 - Intellectual property
 - R&D pipeline and capabilities
-

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Business Development

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11/13/2018

Internally, the plan was called “Project Pearl.” JAN-MS-01051754. Janssen and Purdue were scheduled to meet again for a discussion about partnership alternatives on September 6, 2000. JAN-MS-01051754. Janssen internally discussed three options: Reciprocal co-promotion rights on all brands, R&D partnership for development of new brands, Joint Venture to create stand-alone pain company. JAN-MS-01051754. Janssen determined ultimately to present the reciprocal co-promotion idea, with a financial structure that revenue and profit split on all brands, J&J heavier on revenue and Purdue heavier on profit. JAN-MS-01051754. A J&J “next step” was to develop a “one Pain Sales force” configuration for J&J and the company began internally restructuring

around this time. Likewise, a June 9, 2000, PPT slide depicts Janssen's analgesic pain spectrum portfolio including OxyContin. JAN-MS-00785194.

A July 28, 2000 email from Michael Grissinger to several others at Janssen discusses the impending September meeting with Purdue to "explore ways in which we might work together in pain management." JAN-MS-01052165. Grissinger asks that the information be kept confidential. JAN-MS-01052165.

A PowerPoint envisioning mirrored sales forces, with all reps carrying both companies' products appears to be what Janssen presented at the September meeting. JAN-MS-00311050.

Potential Purdue/J&J Pain Mgt Sales Force Deploymen

- Mirror Purdue and Janssen sales force
 - Combo territory
 - Fewer JNJ reps needed
- All 5 pain products carried by all representatives
- Rotation of products would develop on 3- to 4-month cycles according to need.

	Purdue N = 700	JNJ N = 700
Primary Care	OxyContin/Palidon Ultracet/SR/DURAGESIC®	Ultracet/SR/DURAGESIC® OxyContin/Palidon
Pain Specialists	OxyContin/Palidon Ultracet/SR/DURAGESIC®	Ultracet/SR/DURAGESIC® OxyContin/Palidon
All other HVPs	OxyContin/Palidon Ultracet/SR/DURAGESIC®	Ultracet/SR/DURAGESIC® OxyContin/Palidon

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Business Development

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11/13/2018

A later, November 2000 PPT shows Janssen discussing co-promotion opportunities with Knoll and, curiously, that PPT shows the imagined Janssen/Purdue sales force as part of the deal, per below. JAN-MS-00456095.

Proposed Knoll/ J&J Deployment

- Mirror Knoll and J&J sales forces
 - Combo territories
 - Sales representatives will be trained in all 5 products but carry 3
- Four sales forces of 350 representatives--2 each from Purdue and J&J
 - Allows for maximum flexibility to deliver 5 products in priority position
 - Each sales force can reach 60,000 physicians individually
 - Frequency goals attained by overlapping of physicians
 - 2.02 million primary positions with 3.23 million PDEs to allocate
- Product priorities will be developed on 3- to 4-month cycles according to need

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11/30/2018

A January 3, 2001 PPT about co-promotional opportunities mentions Purdue Frederick:
“Reviewing how we can work together to help each company achieve maximum sales potential of existing and future products.” JAN-MS-00456093.



Co-Promotional Opportunities

- **PURDUE FREDERICK**
 - Reviewing how we can work together to help each company achieve maximum sales potential of existing and future products
 - Purdue and OMP marketing teams plan to meet to discuss the options to work together.
 - Janssen also needs to be involved in these discussions

Janssen acted to protect *all* Schedule II drugs, including OxyContin. On April 20, 2001, Bruce Colligen at Janssen sent an email to Dennis Fitzgerald and others regarding “[t]he OxyContin issue” JAN-MS-00307337. The email worries that state legislatures are responding and suggests drafting legislative language that Janssen’s lobbyists can use “to protect J&J business interest.” JAN-MS-00307337. “We want to be certain that Janssen (Duragesic) does not get caught in the OxyContin web, but we also need to have enough foresight to look towards the future of pain management and not be too limiting.” JAN-MS-00307337. “It is not our policy to advance language that would attack a competitor’s product.” JAN-MS-00307337. The email also acknowledges that the company has fought the issue of triplicate prescription pads and has been successful over the years. JAN-MS-00307337. Abuse issues “make our job more difficult.”

Id. An April 22, 2001 S.W.O.T. Analysis says that the abuse discussion can damage the total market. JAN-MS-00478511

Purdue sent a letter to its entire sales force on April 2, 2000, telling its representatives not to sell OxyContin by talking to doctors about the potential for Duragesic abuse. PKY182107687. “Janssen Pharmaceuticals and Purdue have agreed that should either company have representatives who promote product out of label or out of policy, the name of the representative will be provided to the other company for investigation and disciplinary action if necessary.” PKY182107687. Indeed, Friedman and Norton/Gorsky spoke and wrote directly about the issue. PKY181022850; PPLPC009000036199; PKY181103719.

On August 14, 2001, Dennis Fitzgerald, Jim Eckhard, Steve Huber, David Duvall, and Ed Rady and others at Janssen met regarding OxyContin abuse issues to be discussed in front of the FDA advisory board. JAN-MS-00899138. In particular, the group was concerned about whether to get involved in the public debate. “On the plus side, [getting involved] allows us to take a position, not rely on PF [Purdue], and to acknowledge that we are already ‘involved’ by virtue of the product we market.” JAN-MS-00786155. “On the negative side, we will not be involved, we risk getting ‘linked’ with Oxycontin, and we will need to support our position.” JAN-MS-00786155. Purdue decided to take an active role and intended to reach out to John Coleman at the DEA to ask him to submit DAWN database analysis in writing. They say they should either “protect the class [which would include Oxy] from restrictive actions,” actively differentiate Duragesic as less abuse potential, or simply “leaving out our opinions (good and bad) on the use of the class”

The notes later get edited, and the editor suggests, “Advocate for aggressive treatment of pain, defend the class and ‘mention’ that there are multiple types and formulations of opioids, which have different safety/benefit profiles –including . . . Duragesic The key is not to turn

this into a promotional platform (especially since I don't think we have enough data to back up our 'less-abuse-prone' claim." JAN-MS-00899138.

Gary Vorsanger of Janssen would make a three-minute presentation to the FDA. Discovery International, a consulting group, helped to draft the message. "It was suggested that KOLs have a limited awareness as to the scope of the problem; therefore it would be advantageous to prepare a document that follows the story (in the press) over time." JAN-MS-00899138. Janssen internally admitted that its "experts" are not informed on abuse issues.

The next day, a Duragesic Tactical Plan seeks to create the NPEC, to expand further into the non-malignant pain market, to position Duragesic as the first opioid of choice, to "generate" a call to action among patients. JAN-MS-00306713. "Deliver a strong value story for long acting opioids in general and Duragesic specifically." JAN-MS-00306713. This evidences intent to grow the market for OxyContin – after the potential for abuse is understood.

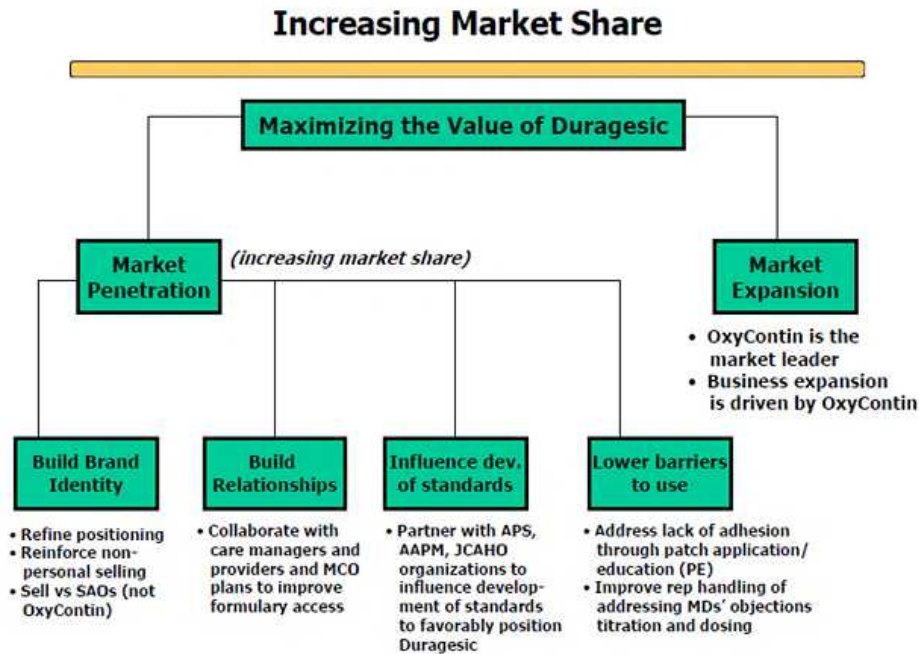
In April of 2001, Purdue created a Partners Against Pain Advocacy Toolkit, essentially a guide to how to control the abuse message, and Janssen ended up with a copy. JAN-MS-00304077.

Purdue and Janssen also had contact through the "Pain Forum" meetings. In October 2002, a save the date for "Pain Forum II" meeting of DEA and industry leaders was sent out. JAN-MS-00386260; JAN-MS-00614872. The meeting was organized by Joranson of the Pain & Policy Studies Group and by Last Acts (RWJF). And in the summer of 2001, the DEA & Joranson had meetings with "select industry members" on OxyContin abuse issues, which resulted in the DEA consensus statement. JAN-MS-00386260.

"The chronic pain market has vastly expanded because of two primary players, Duragesic and Oxycontin." JAN-MS-00299220.

Janssen acknowledges that Oxycontin drives market growth, generally, and drives Duragesic growth, specifically. JAN-MS-00306767; JAN-MS-00299220; JAN-MS-00432716

(Kuntz). Janssen sought to drive patients & prescribers from short-acting opioids to long-acting opioids, like Duragesic. JAN-MS-00494171 at 14 (Moskovitz).

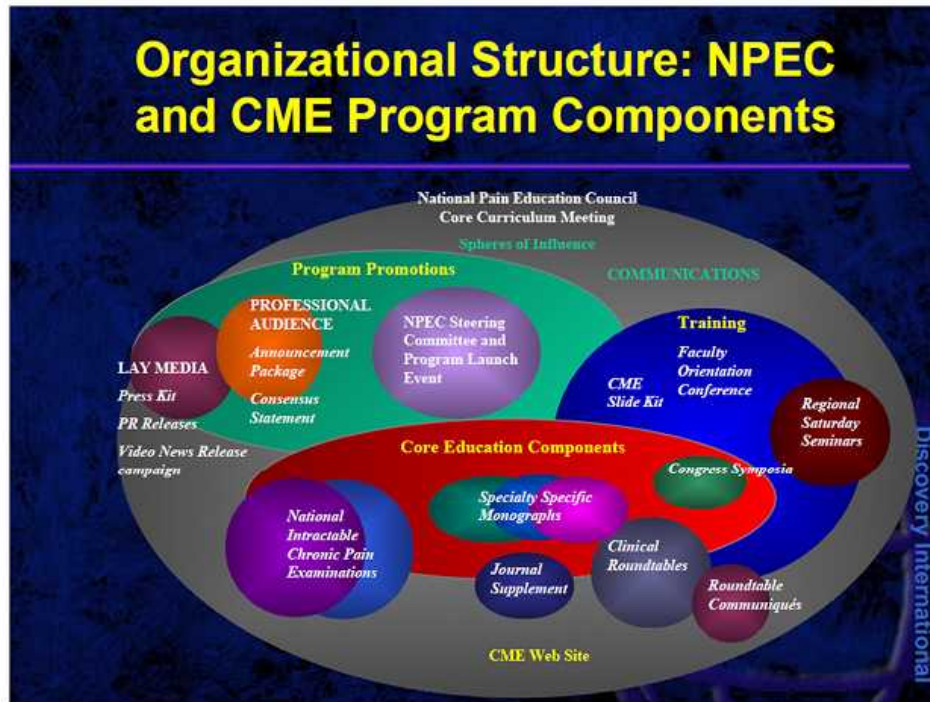


On November 11, 2001, Jeff Mathis wrote that "Oxycontin and Duragesic are responsible for growth [of the Strong Opioid Market]." JAN-MS-02531371. He placed growth at 21%. "Growth of OxyContin was only slowed by concerns over the abuse potential." JAN-MS-02531371. In another document created by McKinsey & Company for Janssen's Global Operations Team on Duragesic Disease Modeling, acknowledging that OxyContin created the market in low back pain, which is where Duragesic wants to position itself. JAN-MS-00432716 at 4. A Janssen request for research proposals tacitly acknowledges that competitor sales can expand the chronic pain market. JAN-MS-00305722. Further, a 2002 Duragesic business plan states that Purdue is an attractive co-promotion partner. JAN-MS-00310227 at -84.

Even when competing, Purdue recognized the companies helped each other: “We will produce and create programs that will generate interest and growth in Pain management, and so will [Janssen]. In some cases some of the things they do will help us, and vice-versa.” PPLPC009000079874.

Janssen spent millions creating the National Pain Education Council (“NPEC”) with the help of Discovery International (AKA: Discovery East, LLC) (“Discovery”) sometime around August 2001 as part of the Duragesic Tactical Plan. JAN-MS-00306713. According to an “Agency Performance Survey,” an internal review, Discovery became Janssen’s “medical education agency of record” in September 2000. JAN-MS-00781342. “The Discovery East team is dedicated to the overall management of the brand, not only execution of the actual tactics.” JAN-MS-00247190. Kathleen “Kati” Chupa, who looks to have been Discovery’s handler, deemed its programs “effective and aligned with brand strategies.” JAN-MS-00781342.

Janssen’s vision for the NPEC was comprehensive, as shown by the following slide:



JAN-MS-00306713. The organization was to be endorsed by APS, AAPM, and “other pertinent medical societies.” JAN-MS-00306713. The timeline for the project can be found at JAN-MS-00314040.

Critically, the NPEC was to be (and was) co-chaired by Dr. Russell Portenoy (APS President) and Dr. Richard Payne, with numerous other doctors and a JCAHO representative sitting on its executive committee and peer review committee. JAN-MS-00306713. June Dahl of PPSG was also involved. According to January 2003 meeting notes, it appears that Drs. Payne and Portenoy were to be paid “\$15M” individually and “\$25M” to their respective institutions in honorarium. JAN-MS-00312977. The doctors also appear to have met with the DEA in their NPEC capacities. JAN-MS-00777576.

According to a Discovery presentation, its goals for NPEC were to:

- Drive healthcare providers to the NPEC website in 2002
- Initiate the positioning of the NPEC as the premier pain management education program for the medical community
- Position long-acting opioids as preferred therapy for the treatment of chronic pain
- Strengthen Janssen's positioning as a leader in pain management education

JAN-MS-00787624. A 2003 Tactical Plan shows the following NPEC Objectives:

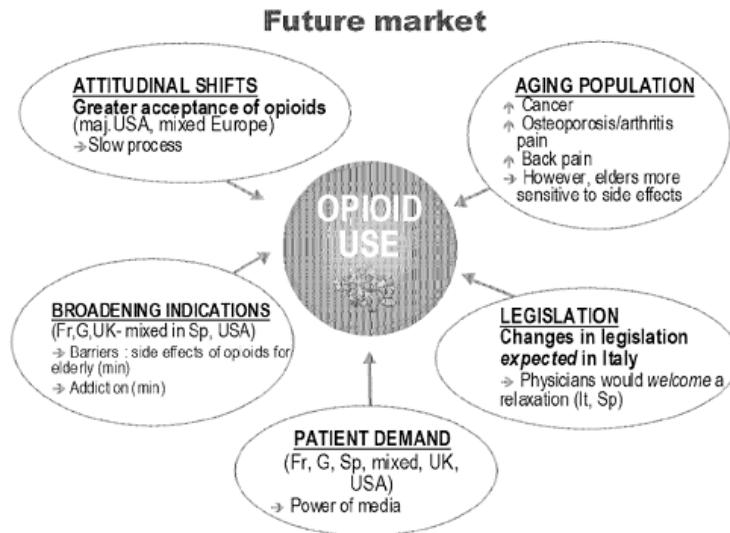
- Establish website as a key educational resource for primary care physicians – specifically on the appropriate use of opioids for pain management
- Position as a referral site for pain specialists to encourage and facilitate education of the expanded pain management team
- Establish as an educational tool in fellowship and residency training programs
- Use as springboard for pain management franchise development
- Position Janssen as a leader in pain management

JAN-MS-00780331. An estimated budget for the year 2003 shows nearly \$10M on NPEC programs. JAN-MS-00306772.

Internally, the NPEC was certainly a top “strategy and tactic” for “position[ing] Duragesic as the optimal LAO choice for non-malignant and malignant pain.” JAN-MS-00494171 at 10-11. And Kati Chmonitorupa was clear that Discovery's work is one method of “leveraging Duragesic dollars for the franchise.” JAN-MS-00726338 (Blockinger).

A website, www.npecweb.org, was eventually created. See https://web.archive.org/web/*/http://npecweb.org/. Janssen disclosed that it funded the NPEC website, it also says that all content is created by the co-chairs. February 2002 meeting notes indicate that that materials for the NPEC program were “derived” from an outline written by Dr. Portenoy and Payne, approved by Discovery and reviewed by Janssen. JAN-MS-00312347. The same notes demonstrate that monographs were written by writers directed by Discovery. JAN-MS-00312347.

A July 2003 presentation lays out how Discovery assisted Janssen in promoting Duragesic at APS, AAPM, and ASPMN symposiums. JAN-MS-02760144. Around the same time, other non-Discovery-related presentations clearly demonstrate that Janssen viewed attitudinal shifts and broadened indications, among other factors, as contributing to increased opioid use/sales:



JAN-MS-00371431 (2002 Taylor Nelson Sofres Report on Duragesic Lifecycle).

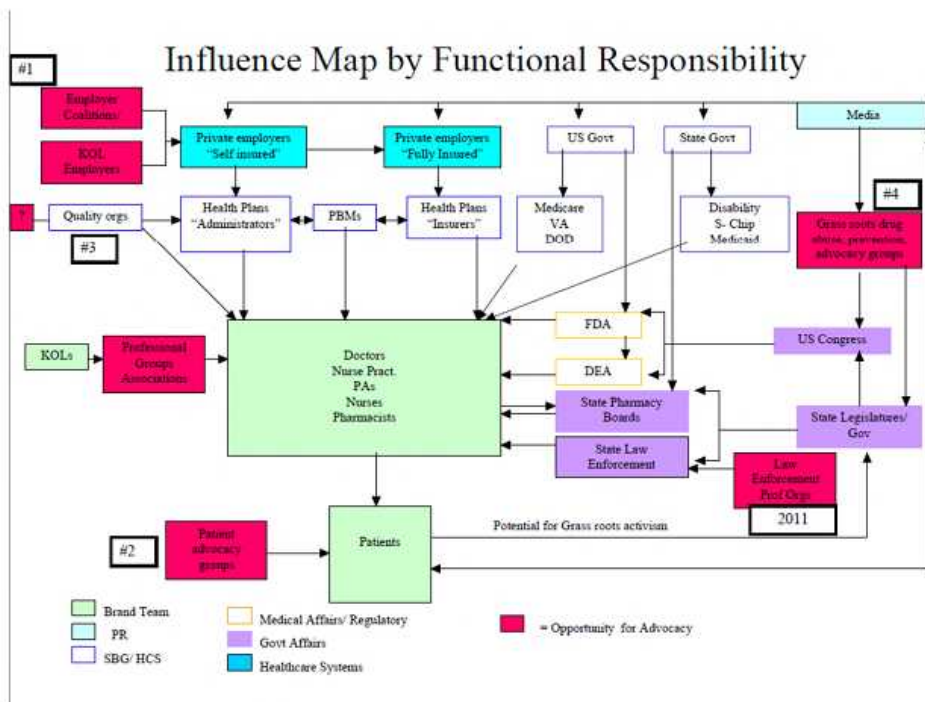


JAN-MS-00306755 (2001 Pain Franchise Review).

In June 2001, Janssen agreed to contribute \$50,000 to fund, with other manufacturers, an “Advanced Pain Management Certification Program” in Florida. JAN-MS-01144712. The program was targeted at pharmacists, and it was seen as a way to overcome their resistance to dispensing opioids. JAN-MS-01144712. The licensing program was viewed as “the first of its kind” and probable to “serve as a reference point for other such programs.” JAN-MS-01144712. In the same email, it is mentioned that the program is consistent with JCAHO objectives “i.e., fifth vital sign.” A 1997 survey funded by the Robert Wood Johnson Foundation that developed the pain 2001 JCAHO standards. David Baker, MD, MPH, *The Joint Commission’s Pain Standards: Origins & Evolution*, THE JOINT COMMISSION (May 5, 2017), https://www.jointcommission.org/assets/1/6/Pain_Std_History_Web_Version_05122017.pdf.


See also JAN-MS-01144714.

From February 2009 AAPM Corporate Council meeting notes, it appears that Cassie Hallberg, Director of Analgesic Stakeholder Relations for Janssen (now a former employee) attended an AAPM meeting where she agreed to identify key professional and patient pain associations and to “map” out those stakeholders and lines of influence to each in order to help AAPM “start a movement.” JAN-MS-00929254. This occurred around the time the REMS Task Force was active. Cassie Hallberg created the “Influence Map,” below. JAN-MS-02494558.



Cassie also had the help of consultants from SmartAnalysis in gathering background data on all the organizational stakeholders. JAN-MS-02494553.

Executive Summary
SMARTANALYST
INTELLIGENT INSIGHTS. SMART RESULTS.

Pain Association	Focus of Mission	Website	Newsletter	Geographic Presence	Number of Members
American Pain Society	High Focus on Pain Treatment <ul style="list-style-type: none"> To increase knowledge of pain and transform public policy and clinical practice to reduce pain-related suffering. 			National (six regional sections)	Over 3,000 (including health professionals, basic scientists, policy makers, and lawyers)
American Pain Foundation	High Focus on Pain Treatment <ul style="list-style-type: none"> To improve the quality of life of people with pain 			National	80,000 (including patients, families and healthcare providers)
American Chronic Pain Association	High Focus on Pain Treatment <ul style="list-style-type: none"> To facilitate peer support and education for individuals with chronic pain and their families. To raise awareness among the health care community, policy makers, and the public at large about issues of living with chronic pain. 			International (more than 800 chapters)	NA
American Academy of Pain Medicine	High Focus on Pain Treatment <ul style="list-style-type: none"> To advance the specialty of Pain Medicine and the comprehensive care of patients with pain. 			National (four state Chapters)	Over 1,300
Alliance of State Pain Initiatives	High Focus on Pain Treatment <ul style="list-style-type: none"> To ensure that peoples' lives are not overpowered by pain. 			National (19 state pain initiatives)	NA



Source: SmartAnalyst

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Cassie Hallberg also prepared a list of influential associations in each region of the country.

JAN-MS-02494558 (Central Region – others attached to JAN-MS-02494552).

Plaintiff reserves the right to supplement or amend its response, and this issue may be the subject of fully-supported and detailed expert witness opinion(s).

Interrogatory No. 8:

Identify any “unbranded advertising” or “unbranded marketing” (as those terms are used throughout the Complaint) disseminated in the Plaintiff’s county, city, village, or township in which any Defendant participated or to which any Defendant contributed in any way. Include in the response the identity of the Defendant(s) that participated or contributed and the identity of the person or persons to whom the “unbranded advertising” or “unbranded marketing” was distributed.

Response:

Plaintiff repeats and reasserts its prior objections and adopts its prior responses to this Interrogatory. Plaintiff objects to this Interrogatory as vague, overly broad and unduly burdensome to the extent it requests Plaintiff to identify any “unbranded advertising” or “unbranded marketing” disseminated in Plaintiff’s jurisdiction in which any Defendant participated or contributed. Plaintiff objects to this Interrogatory to the extent it seeks information that is uniquely in Defendants’ possession.

Notwithstanding and without waiving all objections, Plaintiff responds: Defendants Purdue, Endo and Teva sponsored a publication entitled, *Responsible Opioid Prescribing*, which promoted the prescription of opioids for non-cancer patients. This publication was distributed by Endo sales representatives throughout Plaintiff’s jurisdiction with a special introductory letter from Dr. Scott Fishman. Purdue also promoted its pain-management website – www.InTheFaceOfPain.com – which included testimonials from several paid “advocates” urging more pain treatment. Yet another Purdue unbranded website – Partners Against Pain – stated “Current Myth: Opioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids. Fact: Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids.” “Addiction risk also appears to be low when opioids are dosed properly for chronic, noncancer pain.” Purdue posted an unbranded pamphlet entitled Clinical Issues in Opioid Prescribing on its unbranded website, PartnersAgainstPain.com, in 2005, and circulated this pamphlet through at least 2007 and on its website through at least 2013. The pamphlet listed conduct including “illicit drug use and deception” that it claimed was not evidence of true addiction but “pseudoaddiction” caused by untreated pain.

A Janssen unbranded website – www.PrescribeResponsibly.com – stated that concerns about opioid addiction are “overestimated” and that “true addiction occurs only in a small percentage of patients.” In 2012, Mallinckrodt promoted a book through its unbranded C.A.R.E.S. Alliance website entitled “Defeat Chronic Pain Now!” which stated false claims such as “Only rarely does opioid medication cause a true addiction when prescribed appropriately” and “Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction.” In addition, Defendants sponsored multiple CMEs in or near Plaintiff’s jurisdiction to promote the use of opioids and downplay any risks or adverse effects; including Cephalon-sponsored CMEs made widely available through organizations such as Medscape LLC and a Teva-sponsored CME that was published in a supplement of Pain Medicine News in 2009.

In addition, Cephalon and/or Teva in their branded and unbranded marketing efforts omitted key information on the proper use and risks, including the risks of misuse, abuse and addiction, associated with Actiq and Fentora. Cephalon and/or Teva further failed to take the steps they acknowledged were necessary to ensure safe use of those drugs, as set forth in the Actiq Risk Management Program and the Fentora Riskmap, and the REMS programs for those drugs. *See* TEVA_MDL_A_03272088; TEVA_CHI_00028341; TEVA_MDL_A_08399245; TEVA_MDL_A_01584978; TEVA_MDL_A_07679384; TEVA_MDL_A_07679522. Such steps included using various tools and vehicles, including using their sales force, speakers programs, advertising and publication plans, to convey messaging and to educate doctors about proper patient selection according to their indicated uses, including use only in cancer patients who were opioid tolerant, and about the risks of addiction, misuse and diversion associated with those drugs. *See, e.g.,* TEVA_MDL_A_07424105; TEVA_MDL_A_00267691; TEVA_MDL_A_01583546; TEVA_MDL_A_01583458; TEVA_MDL_A_00038282; TEV_FE00116840. Such steps are

parallel and consistent with the steps Plaintiff claims should have been taken by Cephalon and Teva under Ohio state tort and statutory laws. Cephalon and/or Teva instead used these tools and vehicles in their branded and unbranded marketing to convey messaging and educating doctors to the contrary, including that use of Actiq and Fentora was appropriate for off-label chronic use, use in cancer patients and use in opioid-naïve patient populations, and that the risks of misuse, abuse and addiction were minimal and could be managed.

Further, Cephalon and Teva were and remain aware their name-brand and generic opioid products were being prescribed by doctors and other health care providers for conditions other than their indicated use, and without full knowledge and appreciation of the proper use and risks associated with those opioid products. Cephalon and Teva also were and remain aware once a name-brand opioid product lost its patent protection and generic manufacturers such as Teva entered the market for that generic product (including opioid products), the market share for that product was and remains dominated by the generic manufacturers. Cephalon and Teva also were and remain aware generic manufacturers dominate the overall opioid market, including over 90% of the prescription opioid market as Plaintiffs are informed and believe. Cephalon and Teva also knew at all relevant times that their name-brand and generic opioid products were high-risk Schedule II narcotic prescription products, and as such it was especially important doctors and other healthcare providers be pro-actively educated and informed on the proper use and risks associated with those opioid products, and especially so when they became aware those drugs likely were being improperly prescribed and that patients were becoming addicted. Cephalon and Teva, through their omissions, failed to adequately communicate to doctors and other health care professionals, consistent with their product labels, the proper uses and indications for their name-brand and generic high-risk opioid products, as well as key safety information and risks associated with those opioid products including the risks of misuse, abuse and addiction. Cephalon and Teva's

failure to take adequate steps to communicate proper use and risk contributed to the improper use and over-prescription of their name-brand and generic opioid products, leading to unnecessary and widespread addiction of patients and harm to Plaintiffs.

At least 20 depositions of fact witnesses have been taken of Cephalon and/or Teva witnesses, utilizing hundreds of exhibits. The discovery performed to date, including depositions, written responses and document productions, provides details of statements and omissions made or disseminated that were false, misleading, unfair and deceptive. It is not practicable to specifically identify each and every statement and omission herein. Plaintiff reserves the right to rely upon and introduce as evidence any and all deposition testimony and exhibits addressing this topic. Also, Plaintiff's discovery, document review and investigation are continuing, and it reserves its right to rely upon and introduce further evidence addressing this topic. For purposes of illustration, including by way of examples, Plaintiff supplements its responses as follows:

Cephalon and Teva Teva deceptively marketed opioids through unbranded advertising – i.e., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing and distributing this unbranded advertising, Cephalon and/or Teva coordinated and controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain.

Cephalon and/or Teva marketed opioids through third-party, unbranded advertising to avoid regulatory scrutiny because such advertising is not submitted to and typically is not reviewed by the FDA. Cephalon and/or Teva also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Pro-opioid Key Opinion Leaders (“KOLs”) have admitted to making false claims about the effectiveness of opioids. Dr. Russell Portenoy received research support, consulting fees, and other

compensation from Cephalon, Endo, Janssen, and Purdue, among others. Dr. Portenoy admitted that he “gave innumerable lectures . . . about addictions that weren’t true.” His lectures falsely claimed that fewer than 1 percent of patients would become addicted to opioids. Dr. Portenoy admitted that the primary goal was to “destigmatize” opioids, and he conceded that “[d]ata about the effectiveness of opioids does not exist.” According to Dr. Portenoy, “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.” Dr. Portenoy admitted that “[i]t was clearly the wrong thing to do.” See Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J. (Dec. 17, 2012), available at <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604> (last accessed December 20, 2017).

Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations, such as his claim that “the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low.” He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast across the country, Dr. Portenoy claimed: “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that the person is not going to become addicted.” Good Morning America (ABC television broadcast Aug. 30, 2010).

Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President of the American Academy of Pain Medicine (“AAPM”) in 2013. He is a Senior Editor of Pain Medicine. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo and Purdue. At the same time, Dr. Webster was receiving nearly \$2 million dollars in funding

from Cephalon. Dr. Webster also was a leading proponent of the concept of “pseudoaddiction,” the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster’s description, the only way to differentiate the two was to increase a patient’ dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid Abuse While Managing Pain*—a book that is still available online—when faced with signs of aberrant behavior, increasing the dose “in most cases . . . should be the clinician’s first response.” Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007). Years later, Dr. Webster reversed himself, acknowledging that “[pseudoaddiction] obviously became too much of an excuse to give patients more medication.” John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, (Feb. 18, 2012).

Cephalon and/or Teva also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Cephalon and/or Teva and other Manufacturer Defendants, these “Front Groups” – which include, but are not limited to, the American Pain Foundation (“APF”) and the American Academy of Pain Medicine (“AAPM”) as detailed below – generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. The evidence did not support these guidelines, materials, and programs at the time they were created, and the scientific evidence does not support them today. Indeed, they stand in marked contrast to the 2016 CDC Guideline.

Cephalon and/or Teva utilized multiple Front Groups. Several of the most prominent are described below, but there are many others, including the American Pain Society (“APS”), American Geriatrics Society (“AGS”), the Federation of State Medical Boards (“FSMB”), American Chronic Pain Association (“ACPA”), the Center for Practical Bioethics (“CPB”), the U.S. Pain Foundation (“USPF”) and the Pain & Policy Studies Group (“PPSG”). See generally,

e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep't of Health and Human Servs., (May 5, 2015). Organizations, including the U.S. Senate Finance Committee, began to investigate the American Pain Foundation in 2012 to determine the links, financial and otherwise, between the organization and the opioid industry. The investigation revealed that APF received 90 percent of its funding from the drug and medical-device industry, and "its guides for patients, journalists and policymakers had played down the risks associated with opioid painkillers while exaggerating the benefits from the drugs." Within days, APF dissolved "due to irreparable economic circumstances."

Another front group for Cephalon and/or Teva was the American Academy of Pain Medicine. With the assistance, prompting, involvement, and funding of Cephalon and/or Teva, along with other opioid manufacturers, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Cephalon and/or Teva's deceptive marketing of chronic opioid therapy. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allowed drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Cephalon was a member of this council and presented deceptive programs to doctors who attended this annual event. AAPM's presidents have included top industry-supported KOLs Perry Fine and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation.

In 1996, AAPM and APS jointly issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," which endorsed opioids to treat chronic pain and claimed that the risk of a patients' addiction to opioids was low. Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and, upon information and belief, was taken down from AAPM's website only after a doctor complained. The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society, 13 Clinical J. Pain 6 (1997).

AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain. Roger Chou et al., Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain, 10 J. Pain 113 (2009). Treatment guidelines have been relied upon by doctors, especially the general practitioners and family doctors targeted by Cephalon and/or Teva. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. At least 14 of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from manufacturers including Janssen, Cephalon, Endo, and Purdue. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines

have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited hundreds of times in academic literature, were disseminated in Plaintiff's community during the relevant time period, are still available online, and were reprinted in the Journal of Pain.

Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which suggests that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative prescriptions, or theft. This publication is available today. Available at <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last accessed December 19, 2017).

Cephalon and Purdue sponsored Responsible Opioid Prescribing (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. The 2012 edition of Responsible Opioid Prescribing remains for sale online. See Scott M. Fishman, M.D., Responsible Opioid Prescribing: A Physician's Guide (2d ed. 2012). Pseudoaddiction is fictional. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which claimed that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are

therefore the most appropriate treatment for severe pain. This guide is still available online. See <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last accessed Mar. 1, 2019). These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the “[b]enefits of high-dose opioids for chronic pain are not established” while the “risks for serious harms related to opioid therapy increase at higher opioid dosage.” More specifically, the CDC explains that “there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages.” The CDC also states that there are “increased risks for opioid use disorder, respiratory depression, and death at higher dosages.” The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was “not aware of adequate and well-controlled studies of opioids use longer than 12 weeks.”

Cephalon and/or Teva also engaged in unbranded marketing in the form of websites, including, but not limited to, breakthroughpain.com and painmatters.com. These websites promoted the use of opioids for chronic pain. For example, the website breakthroughpain.com published a “Chronic Pain Assessment Tool”. The website painmatters.com indicates, “Prescription opioid medications are an important part of a treatment plan for many people living with chronic pain...” The website painmatters.com includes cites to publications from the front groups described *supra*.

Websites originated by Cephalon include Actiq.com, Breakthroughpain.com, Cephalonspeaker.com, EmergingSolutionsInPain.com, CephalonPainUniversity.com and ShareYourPain.com. EmergingSolutionsInPain.com contained a tool kit which included the Model Policy for the Use of Controlled Substances for the Treatment of Pain by the Federation of State Medical Boards of the United States, Inc.

ShareYourPain.com launched on May 15, 2010 and top referrals to the site came from paid Google searches, WebMD.com, Caring.com, eHealthSolutions and Coping with Cancer. Additionally, Cephalon promoted its products on websites such as Pain.com.

Teva created PainMatters.com. Teva's Pain Matters website includes a Pain Matters documentary produced by the Discovery Channel in collaboration with seven advocacy organizations including American Academy of Pain Management, American Academy of Pain Medicine, American Chronic Pain Association, American Pain Society, American Society for Pain Management Nursing and the U.S. Pain Foundation for Grace.

Cephalon's 2009 Pain Management Prescribing Guide for Opioid Analgesics contained a section entitled Internet Resources which guided the reader to websites for the American Academy of Pain Medicine (AAPM), American Chronic Pain Association (ACPA), American Pain Foundation (APF), American Pain Society (APS), and Pain and Policies Study Group (PPSG).

Plaintiffs reference the following documents setting forth further information on the Front Groups utilized by Cephalon and/or Teva for the unbranded marketing of their opioid products:

- TEVA_MDL_A_02401119
- TEVA_MDL_A_04313917
- TEVA_MDL_A_01853080
- TEVA_MDL_A_01853081
- TEVA_MDL_A_00565051
- TEVA_MDL_A_06557278
- TEVA_MDL_A_03413816
- Teva-Hassler Exhibit 009

The below referenced document is an example of an email referencing Cephalon's work with the American Pain Foundation to develop tools to raise awareness of Breakthrough Pain.

- TEVA_MDL_A_10070432 – TEVA_MDL_A_10070435

The below referenced document is an example of an email regarding a submission to the American Chronic Pain Association suggesting content for the American Chronic Pain Association's 2005 supplement.

- TEVA_MDL_A_09667462 – TEVA_MDL_A_09667463

The below reference is an example of a document addressing presentation of non-cancer clinical data to the Nurses Advisory Board.

- TEVA_MDL_A_07487782

Supplemental information pertaining to Mallinckrodt:

First, Mallinckrodt's 30(b)(6) designee on marketing, Kevin Webb, confirmed that Mallinckrodt utilized a nationwide marketing approach, and that any marketing and advertising materials developed in that approach would have been used in Ohio. *See* Deposition of Kevin Webb.

Second, Mallinckrodt distributed unbranded pain "pocketcards" in its Generics business that contained the following misrepresentations:

"Addiction rarely occurs unless there is a hx of abuse"

"Most opioid agonists have no analgesic ceiling dose; titrate to relief and assess for adverse effects"

"With older adults, start dose low, go slow, but go!!"

"Use long-acting opioids around the clock for baseline management of persistent pain;
Use short-acting opioids PRN (rescue) for breakthrough pain"

"Two drugs of the same class (eg, NSAIDs) should not generally be given concurrently, however long- and short-acting opioids may be prescribed together"*See, e.g.,* MNK-T1_0002159713, MNK-T1_0002183040, MNK-T1_0001531484.

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Third, with its branded products, Mallinckrodt also used unbranded "PocketGuides" that contained the following misrepresentations:

"Risk of addiction is low" (under acute pain heading)

"Single-entity opioids have no maximum dose but may be limited by side effects"

"Pseudoaddiction" = "Drug-seeking behavior focused on pain relief, due to undertreatment of pain." *See, e.g.*, MNK-T1_0001786865, MNK-T1_0002248919.

In addition, Mallinckrodt participated in conferences and tradeshow in which it engaged in the marketing of generic controlled substances manufactured by Mallinckrodt. *See, e.g.*, Deposition Testimony and Exhibits of Steven Becker, Jane Williams and Bonnie New.

PPLP004149692
PPLP004163244
PPLP004134382
PPLP003277170
PPLP003277170

Plaintiff also incorporates its answers and objections to Manufacturer Interrogatory No. 9 and Distributor Interrogatory No. 27. Plaintiff reserves the right to supplement or amend its response, and this issue may be the subject of fully-supported and detailed expert witness opinion(s).

Interrogatory No. 9:

Identify and describe all statements or omissions made or disseminated in the Plaintiff's county, city, village, or township by any Defendant (or any other person whose statements you attribute, in whole or in part, to a Defendant) that you claim were false, misleading, unfair, deceptive or otherwise actionable. Include in your identification of each statement or omission: (i) the name, employer, and position(s) of the speaker, writer, or other person who issued the statement; (ii) the name(s) and position(s) of the recipient(s) of such statement; (iii) when and where the allegedly false, misleading, or deceptive statement was made; (iv) a description of the

content of the statement; and (v) all reasons you claim the statement was false, misleading, or deceptive.

Response:

Plaintiff repeats and reasserts its prior objections and adopts its prior responses to this Interrogatory. Plaintiff objects to this Interrogatory as vague, overly broad and unduly burdensome to the extent it requests Plaintiff to identify and describe “all” statements or omissions made or disseminated in Plaintiff’s jurisdiction by any Defendant that were false, misleading, unfair, deceptive or otherwise actionable. Further objecting, the Interrogatory contains a reference to an undefined phrase, “otherwise actionable.” Plaintiff further objects to the extent it seeks information that is uniquely in Defendants’ possession or publicly available, and with a specificity that imposes an undue burden on Plaintiff. Hundreds of depositions of fact witnesses have been taken of Defendants and the bellwether fact witnesses, utilizing hundreds of exhibits. Millions of documents have been exchanged. The discovery performed to date, including depositions, written responses and document productions, provides details of statements and omissions made or disseminated that were false, misleading, unfair and deceptive. It is not practicable to specifically identify each and every statement and omission herein. Plaintiffs reserve the right to rely upon and introduce as evidence any and all deposition testimony and exhibits addressing this topic. Also, Plaintiff’s discovery, document review and investigation are continuing, and it reserves its right to rely upon and introduce further evidence addressing this topic.

Notwithstanding and without waiving all objections, Plaintiff responds the following false, misleading, unfair and deceptive statements include:

- I. Defendants’ drugs were different; less addictive or abusable than opioids of the past
 - a. Extended release drugs and/or q12 dosing- had fewer peaks and valleys and less chance of addiction and abuse

- b. Abuse deterrent formulations deter abuse
- c. Abuse deterrent formulations are safer than non-abuse deterrent formulations

II. Concerns about Addictive Nature of Opioids Had been Overblown

- a. Science was now showing they were not as addictive as once thought
- b. True patients in pain cannot get addicted – pain protects against addiction
- c. Signs of addiction as simply symptoms of undertreated pain or “pseudoaddiction”
- d. Problems only occur when opioids are abused or used illegally- addicts are bad people who knowingly abused the drugs, not good people who were seeking treatment for legitimate ailments.
- e. If taken as prescribed risk is almost nonexistent:
 - i. addiction less than 1% or low or rare
 - ii. patients can be easily tapered off opioids
 - iii. dependence is not a significant concern - only physical and easily reversed
- f. Drug abusers and potential addicts can be easily identified and therefore not prescribed opioids, or prescribed opioids and monitored closely
- g. Even patients at high risk of addiction can be safely prescribed opioids by using risk-mitigation strategies such as pain contracts

III. Pain should be treated with opioids as a first resort.

- a. Undertreated pain should be treated with opioids
- b. There is more risk of leaving pain untreated than using opioids to treat pain.
- c. Opioids offer more effective pain control and are safer than alternatives.
- d. Defendants’ opioids will make your life better without risk
- e. No maximum dose- if you are in pain more opioids could be given without additional risk (i.e., “titrate to effect” concept from cancer/palliative care should be used with chronic pain)
- f. Opioids can be prescribed for any pain condition without risk
- g. Opioids can be prescribed for any duration without risk
- h. Opioids can be prescribed to any age group without risk
- i. “Round the clock” dosing should be used for chronic pain rather than “as needed” dosing
- j. “Breakthrough pain” applies to chronic pain, not just cancer pain, and short-acting opioids should be used to supplement long-acting opioids for that reason.

Falsehood	Explanation
The risk of addiction from chronic opioid therapy is low	<p>When it launched OxyContin, Purdue cited in promotional and educational materials a single paragraph from a letter published in 1980 by Dr. Hershel Jick and Jane Porter in the New England Journal of Medicine as evidence of the low risk of addiction to opioids. In fact, Purdue included reference to this letter in a 1998 promotional video entitled, "I got my life back," in which Dr. Alan Spanos states, "In fact, the rate of addiction amongst pain patients who are treated by doctors is much less than 1%."</p> <p>Until April 2012, Endo stated on its website that "...patients treated with prolonged opioid medicines usually do not become addicted;" a statement echoed on the website of its close affiliate, APF. Endo also published and distributed multiple pamphlets and brochures downplaying addiction as it related to opioids. For example, "Living with Someone with Chronic Pain", stated, "Most health care providers who treat people with pain agree that most people do not develop an addiction problem."⁴ Other publications, include but not limited to "Pain: Opioid Facts," "Understanding Your Pain: Taking Oral Opioid Analgesics" and "Pain: Opioid Therapy."</p> <p>Janssen claimed on its unbranded website – www.PrescribeResponsibility.com – that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients." Janssen also published a patient education guide entitled "Finding Relief: Pain Management for Older Adults" describing opioid addiction as a myth and that "many studies show opioids are rarely addictive..." which, until recently, was available online.</p> <p>Cephalon sponsored a 2007 publication from APF entitled "Treatment Options: A Guide for People Living with Pain" which taught that opioid addiction is rare.</p> <p>Actavis published material that claimed it is "less likely" to become addicted to opioids in those who "have never had an</p>

⁴ ENDO-CHI_LIT-00195455.

Falsehood	Explanation
	<p>addiction problem.” The same publication notes that a need for a “dose adjustment” is the result of tolerance, and “not addiction.” A 2007 guide for prescribers published under Actavis’s copyright states that Kadian is more difficult to abuse and less addictive than other opioids.⁵</p> <p>Mallinckrodt created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance in 2010 which promoted a book entitled “Defeat Chronic Pain Now!” in which opioids were stated to “rarely” cause addiction.</p>
To the extent there is a risk of addiction, it can be easily identified and managed	<p>Purdue and Cephalon sponsored the APF’s publication, “Treatment Options: A Guide for People Living with Pain” in 2007, which falsely reassured patients that opioid agreements between doctors and patients can “ensure that you take the opioid as prescribed.” Janssen stated on its website – www.PrescribeResponsibly.com – that opioid addiction “can usually be managed” through tools such as opioid agreements between patients and doctors. Purdue also sponsored a 2011 webinar taught by Dr. Lynn Webster entitled “Managing Patient’s Opioid Use: Balancing the Need and Risk” wherein prescribers were told that screening tools, urine tests, and patient agreements have the effect of preventing “overuse of prescriptions” and “overdose deaths.” Endo paid for a 2007 supplement for continuing education credit in the “Journal of Family Practice” entitled “Pain Management Dilemmas in Primary Care: Use of Opioids” which recommended screening patients and the use of the Opioid Risk Tool.</p>
Signs of addictive behavior are “psuedoaddiction,” requiring more opioids	<p>Cephalon, Endo and Purdue sponsored the Federation of State Medical Board’s (“FSMB”) publication entitled “Responsible Opioid Prescribing” in 2007 which stated that such behaviors as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids and hoarding are all signs of “pseudoaddiction” (not genuine addiction). Purdue published an unbranded pamphlet entitled “Clinical Issues in Opioid Prescribing” in 2005 which was circulated through 2007 and available on its website through 2013. This pamphlet stated that “illicit drug use and deception” were not evidence of true addiction, but rather “pseudoaddiction.” Endo sponsored a CME program in 2009 entitled “Chronic</p>

⁵ ACTAVIS0006823.

Falsehood	Explanation
	Opioid Therapy: Understanding Risk While Maximizing Analgesia,” which promoted pseudoaddiction. Janssen sponsored, funded and edited a website entitled “Let’s Talk Pain” which in 2009 stated that pseudoaddiction “...refers to patient behaviors that may occur when pain is undertreated...”
Opioid withdrawal can be avoided by tapering	Endo sponsored an educational program entitled “Persistent Pain in the Older Adult” which claimed that withdrawal symptoms could be avoided by simply tapering a patient’s opioid dose over ten days. Similarly, Purdue sponsored APF’s publication “A Policymaker’s Guide to Understanding Pain & Its Management” which taught that “[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation.” Neither Defendant explained the significant hardships associated with cessation of use.
Opioid doses can be increased without limit or greater risks	Purdue omitted the increased risk of respiratory distress and death from increasing opioid dosage from its 2010 “Risk Evaluation and Mitigation Strategy” for OxyContin. Endo published on its website a patient education pamphlet entitled “Understanding Your Pain: Taking Oral Opioid Analgesics” that responds to the question, “If I take the opioid now, will it work later when I really need it?” with “The dose can be increased...You won’t ‘run out’ of pain relief.” Purdue and Cephalon also sponsored APF’s 2007 “Treatment Options: A Guide for People Living with Pain” which taught patients that opioids have “no ceiling dose” and are therefore safer than NSAIDs.
Long-term opioid use improves functioning	Janssen promoted Duragesic through an ad campaign as improving a patient’s functioning and work productivity. Janssen’s “Let’s Talk Pain” website featured a video interview claiming that opioids were what allowed a patient to “continue to function.” Similarly, Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association stating, “There Can Be Life With Relief” and implying that OxyContin would help users’ function; however the FDA noted that Purdue failed to warn that patients could die from taking OxyContin. Purdue also ran advertisements in medical journals in 2012 touting that OxyContin would help a “writer with osteoarthritis of the hands” work more effectively. Since May 2011, Endo has distributed and made available on its website – www.Opana.com – a pamphlet implying that patients with physically demanding jobs would achieve long-term pain

Falsehood	Explanation
	relief and functional improvement. Mallinckrodt's website claims that "[t]he effective pain management offered by our [opioids] helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."
Alternative forms of pain relief pose greater risks than opioids	Purdue and Cephalon sponsored APF's publication entitled "Treatment Options: A Guide for People Living with Pain" warning of increased risks if NSAIDs are "taken for more than a period of months;" falsely attributing 10,000 to 20,000 deaths annually to NSAID overdoses when the figure is closer to 3,200. In 2009, Janssen sponsored a publication entitled, "Finding Relief: Pain Management for Older Adults" which listed dose limitations as "disadvantages" of other pain medicines. It also listed a number of serious health effects as disadvantages of NSAIDs while only listing "upset stomach or sleepiness" and constipation as disadvantages of opioids. Purdue and Endo sponsored a CME issued by the AMA in 2003, 2007, 2010 and 2013 entitled "Overview of Management Options" which taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.
OxyContin provides twelve hours of pain relief	In 2000, Purdue advertised that OxyContin provides "Consistent Plasma Levels Over 12 Hours;" however the oxycodone does not enter the body at a linear rate, releasing a greater proportion upon administration and gradually tapering over 12 hours. These 12-hour dosing advertisements ran in the <i>Journal of Pain</i> in February 2005 and the <i>Clinical Journal of Pain</i> in 2006.
New formulations of certain opioids successfully deter abuse	<p>Purdue presented an article in 2013 based on a review of data from poison control centers concluding that its ADF OxyContin can reduce abuse, but failed to acknowledge that abuse merely shifted to other drugs and that there were actually more harmful exposures to opioids after the reformulation. In 2016, Dr. J. David Haddox, VP of Health Policy for Purdue, falsely claimed that the evidence does not show Purdue's ADF opioids are being abused in large numbers.</p> <p>Endo's promotion of its Opana ER also tended to omit material facts according to a May 2012 letter from the FDA to Endo. Endo submitted a citizen petition asking the FDA for permission to label Opana ER as abuse-resistant, and also went so far as to sue the FDA to force expedited</p>

Falsehood	Explanation
	<p>consideration of this change. Endo falsely promoted Opana ER as having been designed to be crush-resistant, knowing that this would (falsely) imply that it was actually crush-resistant and less likely to be abused (as stated in a June 14, 2012 press release). Endo initiated journal advertisements that appears in April 2013 stating Opana ER was “designed to be crush resistant.”</p> <p>Likewise, Actavis copyrighted a guide for prescribers representing that Kadian is more difficult to abuse and less addictive than other opioids.⁶ Mallinckrodt promoted both Exalgo and Xartemis XR as specifically formulated to reduce abuse, going so far as to state, “XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients.”</p>
Endo: “[M]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted.” <i>Taking a Long-Acting Opioid: What Does It Mean to Me</i> (2008); Caregiver Booklet (2009).	This is demonstrably false and misleading.

Subject to and without waiving all objects, Plaintiff identifies the following recipients of false, misleading or deceptive statements from Defendants within Plaintiff’s region: Dr. Michael M. Hughes (President, Summa Health System), Dr. Kendrick Bashor (Physician, University Primary Care Practices, Inc.), Dr. Michael Louwers (Physician, Physical Medicine Rehabilitation), Dr. William Lonsdorf (Physician, Suburban South Family Physicians), Dr. Syed Ali (Anesthesiology/Pain Medicine), Dr. William Reed (Physician, Summa Health Medical Group), Dr. Tony Lababidi, and Dr. Clayton Seiple (Physician, Osteopathic Manipulative Therapy

⁶ ACTAVIS0690598.

Specialist, United Health Network). Furthermore, Plaintiff directs Manufacturing Defendants to their call notes and other records of sales activity, which chronicle statements or omissions made within Summit County and Akron.

Plaintiff also refers Defendants to ¶¶ 47 – 147 of the Second Amended Complaint.

For purposes of illustration, including by way of examples, Plaintiff supplements its responses as follows:

Through a massive marketing campaign premised on false and incomplete information, Cephalon and/or Teva engineered a dramatic shift in how and when opioids are prescribed. Cephalon and/or Teva asserted that the risk of addiction was low when opioids were used to treat chronic pain, and overstated the benefits and trivialized the risk of long-term opioid use. Cephalon and/or Teva's goal was simple: to dramatically increase sales by convincing doctors to prescribe opioids not only for the kind of severe pain associated with cancer in opioid-tolerant patients, but also for common chronic pains, such as back pain and arthritis. They did this even though they knew that opioids were addictive and subject to abuse, and that their claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded.

Through their publications and websites, endless stream of sales representatives, "education" programs, and other means, Cephalon and/or Teva dramatically increased their sales of prescription opioids and reaped billions of dollars of profit as a result.

Cephalon and/or Teva employed the same marketing plans and strategies and deployed the same messages in and around Ohio, including in Plaintiff's community, as they did nationwide. The deceptive marketing schemes included, among others, (a) false or misleading direct, branded advertisements; (b) false or misleading direct-to-physician marketing, also known as "detailing;" (c) false or misleading materials, speaker programs, webinars, and brochures; and (d) false or misleading unbranded advertisements or statements by purportedly neutral third parties that were really designed and distributed by Cephalon and/or Teva, as discussed in response to Interrogatory No. 8. In addition to using third parties to disguise the source of their misinformation campaign, Cephalon and/or Teva also retained the services of certain physicians, known as "key opinion

leaders” or “KOLs” to convince both doctors and patients that opioids were safe for the treatment of chronic pain.

Cephalon and/or Teva have made false and misleading claims, contrary to the language on their drugs’ labels regarding the risks of using their drugs that: (a) downplayed the serious risk of addiction; (b) created and promoted the concept of “pseudoaddiction” when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (c) exaggerated the effectiveness of screening tools to prevent addiction; (d) claimed that opioid dependence and withdrawal are easily managed; (e) denied the risks of higher dosages; and (f) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent abuse and addiction. Cephalon and/or Teva have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support their claims.

Cephalon and/or Teva have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Cephalon and/or Teva Defendants recruited for their support of their marketing messages, through unbranded marketing and through industry-funded front groups. And even though the Cephalon and/or Teva knew doctors, healthcare professionals and the medical community did not have a medical understanding of opioids and risks of opioid abuse, they did not disseminate messages consistent with their product labels that were designed and intended to instruct doctors on the proper use of their opioid products and underscore the abuse and addiction risks associated with those products in order that they would change their prescribing habits so their products would be safely used.

Cephalon and/or Teva Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were

less likely to be schooled in treating pain and the risks and benefits of opioids and therefore more likely to accept their misrepresentations. By way of example, in February 2001, when Cephalon acquired U.S. marketing rights for Actiq, it “repositioned” and “relaunched” Actiq. Prior to the relaunch, “the marketing directive had been to target oncologists, hematologists and pain specialists, with the emphasis being placed on oncology.” TEVA_MDL_A_00454816 at 824 (Cephalon 2002 Marketing Plan). Cephalon’s strategy was to shift the target market from oncologists to other physicians. *See id.* at 829. Cephalon’s 2002 marketing plan stated, “[w]hile oncologists obviously use Actiq to treat BTCP,” anesthesiologist and pain specialists “may feel comfortable with Actiq’s potential in other pain states regardless of the narrow BTCP indication.” *Id.* at 827. Cephalon cited Actiq’s use for, among other things, lower back pain, adhesions, headache, osteoarthritis, fibromyalgia, rheumatoid arthritis and lupus. *Id.* The 2003 Actiq Marketing Plan targeted anesthesiologists and the PowerPoint presentation by Randy Spokane from the same year highlighted anesthesia, pain management, physical medicine and pain, rheumatologists, neurologists and primary care physicians. *See* TEVA_CHI_00042882 at 895; TEVA_MDL_A_09062111 at slide 14. Cephalon and/or Teva targeted physicians lacking experience in the use of Schedule II opioids and the treatment of cancer patients, and to patients without malignant cancer and without opioid tolerance. In addition to targeting more physicians, Cephalon’s campaign also focused on breakthrough pain (“BTP”) instead of breakthrough cancer pain (“BTCP”). *See* 2002 National Sales Meeting Power Point (“Cephalon is successfully repositioning Actiq as a viable and uniquely effective BTP treatment option”).

Cephalon and/or Teva promoted the use of opioids for chronic pain through “detailers” – sophisticated and specially trained sales representatives who visited individual doctors and medical staff in their offices – and small group speaker programs. These detailers have spread and continue to spread misinformation regarding the risks and benefits of opioids to hundreds of thousands of

doctors, including doctors in Ohio. For example, on information and belief, the Cephalon and/or Teva's detailers falsely and misleading state the following:

- a. Described the risk of addiction as low or failed to disclose the risk of addiction. For example, the training modules used to educate Cephalon and Teva's sales force taught that in patients without personal or family history of substance abuse, addiction resulting from exposure to opioid therapy is uncommon. *See* TEVA_MDL_A_00890304 at 354. The training modules also stated that pain appears to reduce the euphoric effects of opioids, so people taking opioids to manage their pain may be at lower risk for addiction. *See* TEVA_MDL_A_00890304 at 358.
- b. Describe their opioid products as "steady state" – falsely implying that these products are less likely to produce the high and lows that fuel addiction – or as less likely to be abused or result in addiction;
- c. Tout the effectiveness of screening or monitoring patients as a strategy for managing opioid abuse and addiction;
- d. State that there is no maximum dose and that doctors can safely increase doses without disclosing the significant risks to patients at higher doses;
- e. Discuss "pseudoaddiction". For example, the training modules used to educate Cephalon and/or Teva's sales force indicated patients in pain do not usually become addicted to opioids. The modules taught the sales force that if patients receive inadequate pain relief, they may exhibit drug-seeking behaviors, i.e. pseudoaddiction. *See* TEVA_MDL_A_00890304 at 358; Day Depo. 160:23 to 161:8. Other Cephalon and/or Teva employees also misled Ohio sales representatives and physicians on the topic of pseudoaddiction. Randy Spokane taught that pseudoaddiction means patients aren't psychologically or physically addicted, they are just in fear of running out of medication. Spokane Depo. 102:5-23; Morreale Depo. 73:3 to 76:8;
- f. State that patients would not experience withdrawal if they stopped using their opioid products;
- g. State that their opioid products are effective for chronic pain without disclosing the lack of evidence for the effectiveness of long-term opioid use; and
- h. State that abuse-deterrent formulations are tamper- or crush-resistant and harder to abuse or misuse.

Because these detailers must adhere to scripts and talking points drafted by the Teva, it can be reasonably inferred that most, if not all, of Cephalon and/or Teva's detailers made and continue to make these misrepresentations to the thousands of doctors they have visited and continue to visit. Cephalon and/or Teva have not corrected this misinformation.

By way of example, Cephalon's 2003 Marketing Plan states, "most pain experts believe that pain is pain regardless of the source of the pain or disease state. Therefore, messaging for both targeted segments, pain specialists and oncologists, will be identical and will include the key marketing messages" TEVA_CHI_00042882 at 933. The marketing plans were shared with the sales representatives, who utilized this information during direct sales calls to Ohio physicians. *See* Sippial Dep. Tr. 91:13-93:16. The marketing message "pain is pain" was utilized with the sales force. *Kaisen Dep. Tr. 25:9-17*. Cephalon also distributed coupons for free Actiq samples or coupons to doctors, some of whom passed them on to non-cancer patients.

For example, the documents produced in this litigation show that Cephalon and/or Teva identified "opiophobia" as a potential roadblock to the sale of Actiq and Fentora. *See* TEVA_MDL_A_09061553 at slide 21; TEVA_MDL_A_09062111 at slide 17; TEVA_CHI_00043010 at 012 and 016. The marketing team and sales force for Cephalon and/or Teva fought the physicians' fear of opioids (i.e. opiophobia) by training sales representatives to discuss opioids with physicians and to reassure them of their safety. The sales force was trained to tell physicians that Cephalon and/or Teva's opioid products had "less potential for abuse" and a "cleaner profile." *See* TEVA_MDL_A_09062111 at slides 11 and 12. Cephalon and/or Teva's marketing and sales teams were taught, and passed along the message to prescribers, that "undertreatment of pain is a widespread problem because of opiophobia." *See* TEVA_CHI_00043010 at 016. For example, Cephalon and/or Teva sales representative, Valerie Kaisen, testified that opiophobia was always a concern. *See* Kaisen Dep. Tr. 144:19-145:4.

The Cephalon and/or Teva sales' force was trained using modules which contained misrepresentations and omissions that were subsequently communicated to physicians. For example, Matthew Day's training of sales representatives included a strategy to "allay [the] fear

of opioids.” *See* TEVA_MDL_A_08657218. Mr. Day used the term opiophobia with the sales representatives he trained, including those calling on Ohio physicians.

Cephalon and/or Teva also identified doctors to serve, for payment and other remuneration, as Key Opinion Leaders (“KOLs”) and on their speakers’ bureaus and to attend programs with speakers and meals paid for by the Cephalon and/or Teva. These KOLs and speakers gave the false impression that they were providing unbiased and medically accurate presentations when they were, in fact, presenting a script and messaging prepared by Cephalon and/or Teva. These presentations conveyed misleading information, omitted material information including about the proper use and risks of their opioid products or the products used to treat, and failed to correct prior misrepresentations about the risks and benefits of opioids. For example, KOLs like Dr. Steven Simon and Dr. Steven Singer were hired by Cephalon to serve as speakers at National Consultants’ Meetings in places like New Orleans. These meetings were also attended by Cephalon employees, including marketing personnel and sales representatives. During these meetings, Dr. Steven Simon spoke on Pain Management Application: Chronic Back Pain/Arthritic Pain. Dr. Steven Singer spoke on Pain Management Application: Migraine Headache. Cephalon and/or Teva paid third party medical marketing firms and physicians to help promote Actiq and Fentora. *See* 2004 Actiq Marketing Sales Training, July 2004 (crediting Cephalon’s success, in part, to “Lots! MedEd”). The educational programs sponsored by Cephalon focused on expanding awareness of BTP and other forms of non-cancer pain. *See* TEVA_CHI_00042882 at 937; *see also* Actiq Consultants Meeting: Event Evaluation.

The Department of Justice also took note of this in its September 29, 2008 Press Release, stating, “[Cephalon] funded continuing medical education programs, through millions of dollars in grants, to promote off-label use of its drugs, in violation of the FDA’s requirements,” and in its memorandum supporting Cephalon’s guilty plea. Press Release, U.S. Dep’t of Justice,

Biopharmaceutical Company, Cephalon, to Pay \$425 million & Enter Plea To Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), and Government's Memorandum For Entry of Plea and Sentencing filed on September 29, 2008 in *United States of America v. Cephalon, Inc.*, Crim. No. 08-598 (and attachments thereto).

Marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Frequent prescribers are generally more likely to have received a detailing visit, and in some instances, infrequent prescribers of opioids received a detailing visit from Cephalon and/or Teva's detailer and then prescribed Cephalon and/or Teva's opioid products. The sales representatives from Cephalon and/or Teva would use sales reports to vet physicians as "growth targets." See Gillenkirk Dep. Tr. 45:2-46:14. These reports included doctors' use of opioids and specialties as factors for potential sales.

Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for, or has been shown to be safe or effective for, chronic pain. Indeed, the FDA prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm. Despite this, Cephalon conducted a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. See Press Release, U.S. Dep't of Justice, Biopharmaceutical Company, Cephalon, to Pay \$425 million & Enter Plea To Resolve Allegations of Off-Label Marketing (Sept. 29, 2008). In September 2008, Cephalon agreed to plead guilty to the charge that it introduced "into interstate commerce . . . drugs that were misbranded through off-label promotion, . . . arising from Cephalon's off-label promotions of its drugs" including Actiq. See Sept. 29, 2008 Department of Justice Press Release ("Cephalon promoted

Actiq for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy. . . [i]t trained its sales force to disregard the restrictions of the FDA-approved label, and to promote the drugs for off-label use.”).

As part of this campaign, Cephalon used speaker programs and KOLs as referenced above, as well as Continuing Medical Education, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. See “Actiq Publication Project Monthly Status Update,” August 2, 2004 (listing publications with topics including a comparison of oral transmucosal fentanyl citrate (“OTFC”) and morphine and the use of OTFC for migraine headaches and musculoskeletal pain).

Cephalon and/or Teva also trained, paid and utilized its Speakers, KOLs and sales representatives to present on and/or provide to doctors and other health care providers studies and journal articles generated by Cephalon and/or Teva for off-label uses of Actiq and Fentora, and did not provide sufficient information on the proper use and risks associated with those products. For example, Dr. Arvind Narayana and others authored clinical studies to promote the off-label use and treatment of Fentora by minimizing the risk of off-label use and providing their evidence of the similarities between cancer BTP and non-cancer BTP. Fentora sales representatives were also permitted to distribute information regarding Fentora’s safety and efficacy in neuropathic and back pain to HCPs who inquired about the off – label use of Fentora. See Portenoy et. al., *Fentanyl Buccal Tablet (FBT) for Relief of Breakthrough Pain in Opioid - Treated Patients with Chronic Low Back Pain: A Randomized, Placebo – Controlled Study*; Simpson et. al., *Fentanyl Buccal Tablet for Relief of Breakthrough Pain in Opioid - Treated Patients with Chronic Neuropathic Pain: A Multicenter, Randomized, Double Blind, Placebo Controlled Study*.

Another element of Cephalon and/or Teva's marketing plan was to ensure reimbursement and insurance coverage for Actiq and Fentora prescriptions for off-label uses. The companies created a reimbursement assistance program designed to help patients obtain insurance coverage for Actiq and Fentora. In 2005, Cephalon reported that managed care organizations had increased restrictive measures on the reimbursement of Actiq but "managed care has, for the most part, been relatively unsuccessful at slowing or stopping Actiq[.]" See TEVA_CHI_00043010 at 043.

Cephalon and/or Teva capitalized on the off-label marketing of Actiq by focusing on Actiq prescribers in order to market Fentora as a better drug, without adequately informing physicians of the drug's cancer indication and addiction risks. Cephalon implemented a plan to transition doctors from Actiq to Fentora starting in 2006 (when Actiq began to face generic competition and Fentora was approved for the same limited indication as Actiq), even though they knew that most of those doctors were prescribing Actiq for off-label uses and did not fully understand the misuse, abuse and addiction risks associated with those drugs. They did this by convincing them that Fentora was a better and faster-acting medication. Cephalon and/or Teva's Fentora marketing plans from 2005 to 2012 basically follow the same off-label marketing roadmap charted for Actiq, and Cephalon considered its transition from Actiq to Fentora a marketing success.

Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses. For example:

- a. Cephalon paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "[c]linically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain.
- b. Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

- c. In December 2011, Cephalon widely disseminated a journal supplement entitled “Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)” to Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for “multiple causes of pain” – and not just cancer pain.

Cephalon and/or Teva disseminated these deceptive marketing and sales messages on a national basis, including in the State of Ohio. During their depositions, Randy Spokane, Michael Morreale and Matt Day all discussed the training of sales representatives and detailers who called on physicians in Ohio and marketing tactics used in the State of Ohio. *See* Spokane Dep. Tr. 16:18-23; 17:17-18:22; 21:14-20; 43:16-20; Morreale Dep. Tr. 13:14-14:17; 16:22-25; and Day Dep. Tr. 316:6-16; 319:24-320:8; *see also* depositions of Colleen Gillenkirk, Valerie Kaisen and Laura Sippial (Cephalon/Teva sales representatives discussing their detailing activities in Ohio). At annual sales meetings, the sales and marketing plans for Actiq and Fentora were shared. *See* Spokane Dep. Tr. 62:15-23.

In addition, Cephalon and/or Teva in their branded and unbranded marketing efforts omitted key information on the proper use and risks, including the risks of misuse, abuse and addiction, associated with Actiq and Fentora. Cephalon and/or Teva further failed to take the steps they acknowledged were necessary to ensure safe use of those drugs, as set forth in the Actiq Risk Management Program and the Fentora Riskmap, and the REMS programs for those drugs. *See* TEVA_MDL_A_03272088; TEVA_CHI_00028341; TEVA_MDL_A_08399245; TEVA_MDL_A_01584978; TEVA_MDL_A_07679384; TEVA_MDL_A_07679522. Such steps included using various tools and vehicles, including using their sales force, speakers programs, advertising and publication plans, to convey messaging and to educate doctors about proper patient selection according to their indicated uses, including use only in cancer patients who were opioid tolerant, and about the risks of addiction, misuse and diversion associated with those drugs. *See*,

e.g., TEVA_MDL_A_07424105; TEVA_MDL_A_00267691; TEVA_MDL_A_01583546; TEVA_MDL_A_01583458; TEVA_MDL_A_00038282; TEV_FE00116840. Such steps are parallel and consistent with the steps Plaintiffs claim should have been taken by Cephalon and Teva under Ohio state tort and statutory laws. In fact, as set forth herein, Cephalon and/or Teva instead used these tools and vehicles in their branded and unbranded marketing to convey messaging and educating doctors to the contrary, including that use of Actiq and Fentora was appropriate for off-label chronic use, use in cancer patients and use in opioid-naïve patient populations, and that the risks of misuse, abuse and addiction were minimal and could be managed.

Further, Cephalon and Teva were and remain aware their name-brand and generic opioid products were being prescribed by doctors and other health care providers for conditions other than their indicated use, and without full knowledge and appreciation of the proper use and risks associated with those opioid products. Cephalon and Teva also were and remain aware once a name-brand opioid product lost its patent protection and generic manufacturers such as Teva entered the market for that generic product (including opioid products), the market share for that product was and remains dominated by the generic manufacturers. Cephalon and Teva also were and remain aware generic manufacturers dominate the overall opioid market, including over 90% of the prescription opioid market as Plaintiffs are informed and believe. Cephalon and Teva also knew at all relevant times that their name-brand and generic opioid products were high-risk Schedule II narcotic prescription products, and as such it was especially important doctors and other healthcare providers be pro-actively educated and informed on the proper use and risks associated with those opioid products, and especially so when they became aware those drugs likely were being improperly prescribed and that patients were becoming addicted. Cephalon and Teva, through their omissions, failed to adequately communicate to doctors and other health care professionals, consistent with their product labels, the proper uses and indications for their name-

brand and generic high-risk opioid products, as well as key safety information and risks associated with those opioid products including the risks of misuse, abuse and addiction. Cephalon and Teva's failure to take adequate steps to communicate proper use and risk contributed to the improper use and over-prescription of their name-brand and generic opioid products, leading to unnecessary and widespread addiction of patients and harm to Plaintiffs.

Supplemental information pertaining to Mallinckrodt:

First, Mallinckrodt's 30(b)(6) designee on marketing, Kevin Webb, confirmed that Mallinckrodt utilized a nationwide marketing approach, and that any marketing and advertising materials developed in that approach would have been used in Ohio. See Deposition of Kevin Webb.

Second, Mallinckrodt distributed unbranded pain "pocketcards" in its Generics business that contained the following misrepresentations:

"Addiction rarely occurs unless there is a hx of abuse"

"Most opioid agonists have no analgesic ceiling dose; titrate to relief and assess for adverse effects"

"With older adults, start dose low, go slow, but go!!"

"Use long-acting opioids around the clock for baseline management of persistent pain; Use short-acting opioids PRN (rescue) for breakthrough pain"

"Two drugs of the same class (eg, NSAIDs) should not generally be given concurrently, however long- and short-acting opioids may be prescribed together." *See, e.g.,* MNK-T1_0002159713, MNK-T1_0002183040, MNK-T1_0001531484.

Third, with its branded products, Mallinckrodt also used unbranded "PocketGuides" that contained the following misrepresentations:

"Risk of addiction is low" (under acute pain heading)

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"Single-entity opioids have no maximum dose but may be limited by side effects"

"Pseudoaddiction" = "Drug-seeking behavior focused on pain relief, due to undertreatment of pain."

See, e.g., MNK-T1_0001786865, MNK-T1_0002248919.

In addition, Mallinckrodt participated in conferences and tradeshow in which it engaged in the marketing of generic controlled substances manufactured by Mallinckrodt. See, e.g., Deposition Testimony and Exhibits of Steven Becker, Jane Williams and Bonnie New.

Bates #	Date	Summary
ACTAVIS0584744	3/11/2006	Kadian Market Opportunity presentation prepared for Alpharma Inc. demonstrates that abuse-resistant formula was to fill this market demand ACTAVIS0584779-788 states that prescriber concerns mostly revolve around abuse - ACTAVIS0584795 SimOpt creates market simulations for Kadian's ability to perform under various scenarios against other abuse-deterrent formulas -ACTAVIS0584807 sees an opportunity in that the "market for abuse-resistant LA opioids is far larger than
ACTAVIS0006823	3/31/2007	2007 Kadian Sales/Marketing brochure "Through its "Learn More about customized pain control with Kadian" material, Actavis claimed that it is possible to become addicted to morphine-based drugs like Kadian, but that it is "less likely" to happen in those who "have never had an addiction problem." Without using the term pseudoaddiction directly, the piece goes on to advise that a need for a "dose adjustment" is the result of tolerance, and "not addiction." (pg. 4).
ACTAVIS0704298	8/29/2007	(See also ACTAVIS0947851, date of documents unclear) "Kadian and Tapering of Opioids" - "In chronic pain patients, and in opioid-tolerant cancer patients, the administration of Kadian should be guided by the degree of tolerance manifested. Physical dependence, per se, is not ordinarily a concern when one is dealing with a patient in

Bates #	Date	Summary
		pain, and fear of tolerance should not deter using adequate doses to adequately relieve pain." *Alpharma pharmaceuticals has not specifically studied the tapering of Kadian in any clinical trial, however the following information may assist you in forming your own conclusions and decisions regarding the use of Kadian.
ACTAVIS0800033	9/18/2007	Kadian Abuse and Dependence - "Addiction to opioids prescribed for pain management is rare..." "In chronic pain patients...the administration of Kadian should be guided by the degree of tolerance manifested. Physical dependence, per se, is not ordinarily a concern when one is dealing with a patient in pain, and fear of tolerance should not deter using adequate doses to adequately relieve pain." Part of 38-doc zip drive attachment to email at ACTAVIS0799930 - 2/1/2012 - from Ntomy to Guinto-Laput containing "all the medical issue modules for Kadian"
ACTAVIS0585072	10/2/2007	Kadian Vocal Response Listing 8/29/07-10/02/07 List of data regarding calls with doctors to poll them on what Kadian sales reps told them. Examples of questions: What was the main message of the presentation; please describe the type of patients to whom you have given the cards...Same questions posed regarding Avinza formulary» «this primary care provider remembers hearing from Kadian sales rep that there is a low potential for addiction»«doctor mentions rep telling him there is a low incidence of potential for addiction» «doctor remembers the oral sustained action capsule compared to the pill makes it better (from a safety standpoint) for abuse» «Kadian is described as not having an addictive potential» «sales rep apparently said Kadian isn't a drug that would be posing high risk for addiction as compared to OxyContin as obvious from available data» «doctor says he prescribes Kadian because it seems to be less likely to be

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Bates #	Date	Summary
		abused than OxyContin and that those coming in with addict.
ALLERGAN_MDL_00440906	1/15/2009	Sales Call Visual Aid Testing - Qualitative Research – is an analysis of what a group of prescribers thought of Kadian literature - demonstrates that Actavis put resources into tracking and analysing prescriber behavior and how they could utilize the knowledge to increase prescriptions of opioids and promoted the value of opioids to prescribers ALLERGAN_MDL_00440919 "More reasons for morphine" ALLERGAN_MDL_00440931 (pgs 24-26) shows they were pushing doctors to prescribe for "old knee injury" or neck pain from working at a computer.
ALLERGAN_MDL_01100743	1/27/2009	"Actavis - Kadian_Coupon_2009_Program.pdf" - Continuation of Kadian co-pay assistance program with attached copy. Pg. 4: "Many Americans suffer from chronic or ongoing pain. It can cause you to miss work and can even keep you from enjoying life."
ALLERGAN_MDL_01113325	10/13/2009	"Highlights of Kadian v competition" doc touts safety and efficacy of Kadian, which has fewer peaks and valleys and is readily available on more formularies.
ALLERGAN_MDL_01113320	10/13/2009	Kadian Telesales Script -- "Call Introduction" script. It includes guidance on how to pitch Kadian to nurses and/or physicians.
ALLERGAN_MDL_00437891	4/7/2010	Latest Draft] "Managing Chronic Pain and the Importance of Customizing Opioid Treatment" "Set dose levels on basis of patient need, not on predetermined maximal dose." Also, "Opioids can be used with minimal risk in chronic pain patients without a history of abuse or addiction." "Opioids Can Be a Safer Option Than Other Analgesics," cites amongst other things, the danger acetaminophen can cause to the liver. "Improves QOL for patients, helping to maintain elevated mood, sleep, enjoyment of

Bates #	Date	Summary
		life, vitality, social functioning, and mental health."
ACTAVIS1131491	6/16/2010	emails RE: FDA warning letter (on Kadian) In part, Actavis needs to visit approx. 10,000-11,000 physician offices to distribute corrective info. As a result Actavis is postponing sales meeting until corrective action plan is completed.
ALLERGAN_MDL_00436784	6/25/2010	Kadian Learning System, "Drug Abuse and Chronic Pain" chapter - details how until the 1980s "medical (and particularly state board of medical examiners) dogma was that the long-term use of opioids for chronic benign pain was always inappropriate. Practitioners who prescribed long-term opioid therapy, other than for cancer patients were frequently investigated and sanctioned." Goes on to detail how when that changed, diversion became an issue. Marked hot for knowledge of diversion and addiction risks, as well as evidence that Defendants intentionally subverted thousands of years of medical knowledge on opioids to "flip the script." Propaganda crafted to support Defendants position that opioid therapy is beneficial and addiction is manageable. See also ACTAVIS0580642 / ACTAVIS0989088 / ACTAVIS0205095
ACTAVIS0826070	6/30/2010	Patient Information Leaflet says that "Buprenorphine hydrochloride sublingual tablets contain a narcotic painkiller that can be a target for people who abuse prescription medicines or street drugs." ACTAVIS0826071: "Buprenorphine may give you less of a 'high' than these other prescription medicines and street drugs. Withdrawal or stopping buprenorphine may be easier than stopping other prescription medicines and street drugs." ACTAVIS0826073: "You can develop dependence from taking buprenorphine hydrochloride sublingual tablets, and so you may get withdrawal symptoms when you stop taking [them]. There is also a chance that you

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		may abuse or get addicted to buprenorphine hydrochloride sublingual tablets..."
ACTAVIS0580642	7/1/2010	"Kadian Learning System" - "It is important to recognize that tolerance and dependence do not indicate addiction. Rather, they are an expected consequence of taking opioids in moderate to high doses for a significant length of time." "Proper use of opioids is not 'maladaptive' nor does it 'interfere with the person's life'; instead, it allows the patient to return to a functional life. However, some chronic pain patients do have a substance abuse problem."
ALLERGAN_MDL_00435944	7/6/2010	"Kadian PI Workshop - ABM Training" - "Concerns about abuse, addiction, and diversion should not prevent the proper management of pain." "Physical dependence and tolerance are not unusual during chronic opioid therapy." "Kadian provides steady blood levels of morphine sulfate with few peaks and valleys. Kadian is available in 8 different strengths and can be titrated in 10mg increments. The availability of these 8 doses provides flexibility in dose selection."
ACTAVIS1131482	7/7/2010	REMS PPT includes info and quotes from interviews with patients & physicians & pharmacies. These quotes/data indicate that most HCPs are not discussing many opioid risks with patients.
ALLERGAN_MDL_01173104	7/8/2010	Family of documents begins with Parent doc - Mass email amongst employees of multiple defendants. Attachments include 4 IWG REMS documents which touch upon multiple key issues in litigation including: REMS strategy, risk mitigation efforts, collaboration of defendants, Side-by-side comparison of the FDA REMS proposal vs. IWG proposal, medication guides, form letters to medical personnel, training guide for prescribers, safety information, and Cover letter to FDA re: industry working group draft REMS.
ACTAVIS0580066	7/31/2010	Letter to Healthcare Professional re: Correction of Drug Information about

Bates #	Date	Summary
		Kadian; specifically as it relates to FDA's Warning Letter. In the Warning Letter, FDA raised the following concerns regarding the material: (1) it omitted and minimized serious risks associated with KADIAN; (2) it broadened KADIAN's indication and failed to present limitations to its approved indication; and (3) it presented unsubstantiated superiority claims. Upon receiving this letter, Actavis immediately ceased using or distributing this material.
ALLERGAN_MDL_00435558	8/3/2010	"Corrective Message Training Kadian Field Sales Team" - One of the ways Actavis responds to FDA warning letter re: misleading promotional materials is by providing additional training to sales. Do not make unsubstantiated effectiveness claims.
ALLERGAN_MDL_00435541	8/6/2010	Actavis template for corrective letter to HCPs in which they admit to downplaying risks, giving over-broad description of drug indications, and making unsubstantiated claims of superiority to other pain relieving drugs.
ALLERGAN_MDL_00435403	8/19/2010	"Kadian Corrective Information Rollout - Training Class InVentiv Health" - Detailed plan for sales force and Actavis to communicate key corrective messages to those who have been exposed to Co-Pay Assistance Program Brochure.
ALLERGAN_MDL_00434909	12/29/2010	"Marketing Overview, Jennifer Altier" "Kadian Message: Safety - Leverage HCP perception of Kadian's safety profile to gain new Rx's as well as to position Kadian as a viable alternative when patients are dissatisfied with the new formulation of Oxycontin. Kadian has a well known safety profile. No product in the LAO class has a label supporting an abuse-deterrence claim."
ACTAVIS0978471	12/31/2010	"Clarifying the Top Objections to a Kadian Capsules Presentation" - "Proper assessment of the patient, proper prescribing practices, periodic re-evaluation of therapy, and proper dispensing and storage are appropriate

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Bates #	Date	Summary
		measures that help to limit abuse of opioid drugs.” *For Internal Training purposes Only
ACTAVIS0367358	4/20/2011	- Cold call script Financial targeting relying on Medicare, see pg. 3 ACTAVIS0367358 at -7360 Instructions to tailor responses to questions as stirring away from any negative or risk awareness. Fair Balance is for the end of the conversation or when they send materials - this leaves open for sales reps to neglect to close with risks.
ALLERGAN_MDL_00643116	4/22/2011	Final Proposal for Risk Minimization Action Plan. ALLERGAN_MDL_00643115 email sending it from Annechino to Nataline. At ALLERGAN_MDL_00643147 - SOAPP (Screener and Opioid Assessment for Patients with Pain) measure helps determine how much monitoring a patient on long-term opioid therapy needs. “Scoring system” approach. At ALLERGAN_MDL_00643151 - info. about Current Opioid Misuse Measure At ALLERGAN_MDL_00643173: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."
ALLERGAN_MDL_00681039	4/25/2011	- Email chain between Rebeco, Plassche, Young, Aprahamiam and others. Rebeco reports that DEA responds to oxycodone quota request with much less than requested - DEA request was due to distribution to illegal market, with people dying monthly in Kentucky – Michael Perfetto says that they "may need to spin this with customers." Aprahamiam agrees on "spin" but says "don't upset the balance" on pushing for additional approval.
ALLERGAN_MDL_00664891	5/9/2011	Attaching the LAO REMS, email chain reads like they are trying to get their story straight. David Brown asks Paul Coplan for "high-level 'minutes' of key decision points and action items, to memorialize them in writing. "That way, we can systematically inform our internal company colleagues of our decisions and approach before the May 12 FDA prep

Bates #	Date	Summary
		meeting without contradicting ourselves.” Allergan_MDL_00664896 - 5/9/2011 - LAO REMS, including Actavis. This document includes a list of key terms and provides important definitions, one of which is “inappropriate prescribing.” In the definition for inappropriate prescribing, it states that off-label prescribing (from the physician) is not, from an industry perspective, inappropriate. It also includes a definition of abuse, misuse and pseudoaddiction.
ALLERGAN_MDL_00641753	5/23/2011	Email between Nataline and Fridriksdottir discussion on the need to develop a “life-cycle strategy” for Kadian’s new strengths.
ACTAVIS0823350	6/2/2011	Emails regarding marketing and development of new strengths: “...the 30 mg is the biggest seller (units) but the 100 mg makes the most sales dollars.”
ACTAVIS0361609	6/28/2011	Qualitative Research Interviews - “Numerous marketing surveys of doctors in 2010 and 2012, for example, confirmed Actavis’s messaging about Kadian’s purported low addiction potential, and that it had less abuse potential than other similar opioids.” See also ACTAVIS0192847 - 3/8/2013 - Kadian Marketing Update
ALLERGAN_MDL_01040653	6/30/2011	“Oxymorphone Hydrochloride ER Tablets - Generic is Now Available” - Electronic Sellsheet. “Abuse and addiction are separate and distinct from physical dependence and tolerance. Physicians should be aware that addiction may not be accompanied by concurrent tolerance and symptoms of physical dependence in all addicts.”
ALLERGAN_MDL_00401004	7/31/2011	Oxymorphone Sales Training Comes following the 2010 FDA warning on Kadian, and looks like emphasis on training that includes problems with opiates. However, the focus is on brand availability with a cursory, obligatory mention of risks. See pg. 13, at - 1016. “Limit conversations regarding the indication of the product or defer to medical affairs as this is not intended to be a

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Bates #	Date	Summary
		risk/benefit discussion. This is merely an availability announcement." See pg. 14, ALLERGAN_MDL_00401017
ACTAVIS0335906	11/17/2011	email from Altier to DeSantis and Leitch - attached is ACTAVIS0335915 - Kadian generic telescript which says that it provides steady blood levels with few peaks and valleys, no ceiling or maximum dose. Also relevant to long-acting/abuse deterrent issues.
ACTAVIS0335906	11/17/2011	attachment at ACTAVIS0335908 - - Email from Altier to DeSantis and Leitch attaches Kadian generic telescript, which says that it provides steady blood levels with few peaks and valleys, no ceiling or maximum dose.
ACTAVIS0799930	2/1/2012	Email from Ntomy to Guinto-Laput, Thapar, Fogelson attaching "all the Medical Information Modules for Kadian." ACTAVIS0799986 - 2/1/2012 - One of the attachments titled "Kadian and Tapering of Opioids" says that "Addiction to opioids prescribed for pain management is rare..." and "In chronic pain patients...the administration of Kadian should be guided by the degree of tolerance manifested. Physical dependence, per se, is not ordinarily a concern when one is dealing with a patient in pain, and fear of tolerance should not deter using adequate doses to adequately relieve pain."
ALLERGAN_MDL_00441731	2/21/2012	Prescriber feedback on sales presentations. Many prescribers report that sales rep said Kadian is safe and that addiction/abuse potential is low. Prescribers also report that sales reps compared Kadian to other drugs.
ALLERGAN_MDL_00048337	7/17/2012	"Kadian Marketing Overview - Sales Representative Training" [similar doc from 10/31/2011] - Kadian does not have a ceiling or recommended maximal dose, especially in patients with chronic pain of malignancy."
ALLERGAN_MDL_01286709	8/29/2012	"NSAIDs and Anti-Inflammatories" Deborah A. Ward, PharmD., BCOP, BCPS - Presentation detailing safety, efficacy, and risks involved in treating pain with NSAIDs

Bates #	Date	Summary
		and Acetaminophen (despite title). Parent email from Ivan Shaw to Jeannette Barrett.
ACTAVIS0841944	8/30/2012	email attaching American Pain Foundation's Pain Week slides. ACTAVIS0841958 / ACTAVIS0841977 – suggests opioid treatment for pain management without offering other substantive options; says addiction occurs in only 3% of chronic pain patients
ACTAVIS0841616	8/30/2012	"Intellectual Honesty and Dishonesty in Opioids for Chronic Pain Management" Presentation touches on several key issues including overstating benefits and downplaying risks, "what is functional improvement?", and "misapplication of pseudoaddiction" (calls it "poor scholarship").
ACTAVIS0841633	8/30/2012	REMS update slides from PainEDU.org, one of many attachments to email from Ivan Shaw to Jeannette Barrett at ACTAVIS0841424 ACTAVIS0841635 Describes the impacts of the "Far-Reaching Public Health Impact of Widespread Opioid Analgesic Abuse/Misuse" mental impairment, unintentional injuries, family stability infections and other health effects. Also relevant to Low Risk of Addiction/Easily monitored ACTAVIS0841636- 8 shows the increasing rate of nonmedical users, state that teens erroneously think that these drugs are safer than "street drugs" - describe "increasing" addiction and diversion problems. (same family) ACTAVIS0841454 Slides re The Rational Use of Opioid Analgesics for Non-Cancer Pain: What Every Prescriber Needs to Know» Disclosures include Charles Argoff as consultant/Independent Contractor for Grunenthal, Depomed, Grant/Research Support from Endo, Honoraria from Depomed, Endo, Janssen, and Speakers Bureau from Endo and Janssen, Reference to APS/AAPM Clinical Guidelines for Use of Chronic Opioid Therapy in Chronic Noncancer Pain Pseudoaddiction definition.

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Bates #	Date	Summary
ACTAVIS0842077	8/30/2012	Pain Week Slides "When does Acute Pain Become Chronic" indicates that opioids decrease functionality, and might even cause chronic pain or further injury.
ACTAVIS1137030	8/31/2012	Email from sales manager to Marketing Director/Manager Jennifer Altier with compilation of marketing suggestions from sales reps of the "West Region". It seems that the sales reps believe that many doctors' offices and possibly pharmacies are confused on Kadian dosing and/or Generic dosing.
ACTAVIS0575027	9/13/2012	Kadian Marketing Update: market research shows doctors believe Kadian has low abuse potential and have "comfort in prescribing to suspected alcohol abusers due to lack of potency loss." See also ACTAVIS0003354 Kadian Marketing Update; dated 9/13/2012 Perception of low abuse potential, targeting elderly. Objection Handling - also shows composite use of conversations with doctors.
ALLERGAN_MDL_00802760	9/13/2012	"Kadian Access Strategy" - Improving access to coverage, including "adding 4 strengths to the 31 preferred drug lists where Kadian is currently covered."
ACTAVIS0228068	9/28/2012	family/attachment: ACTAVIS0228070 - - Kadian website information indicates risk of abuse and addiction - C discusses withdrawal symptoms, says "physical dependence is not the same as drug addiction."
ACTAVIS0690598	10/2/2012	"Kadian and Abuse Potential" is "A guide for prescribers under Actavis' copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide includes the following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and 2) KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of

Bates #	Date	Summary
		morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state." Abuse potential is apparently less because of (a) slow onset of action (b) lower peak morphine levels than equivalent doses of other formulations of morphine (c) longer duration of action (d) minimal fluctuat...
ALLERGAN_MDL_00219529	10/18/2012	Kadian Access Strategy Update. This document discusses strategy and tactics for managed care/Medicare.
ACTAVIS0997492	12/13/2012	Quantitative Testing of Prescriber Knowledge, Attitudes, and Behavior about Extended Release and Long Acting Opioid Analgesic Products safety and use info.
ACTAVIS0197875	2/18/2013	Sales Training Presentation focuses on benefits of Kadian and instructs on how to deal with "objections" from prescribers , mentions "co-pay assistance." ACTAVIS0197874 email from Altier to Killion, to which Presentation is attached.
ACTAVIS0197923	2/18/2013	family at ACTAVIS0197924 - - Kadian Marketing Overview - no "ceiling" on dose, advises to increase until therapeutic endpoint reached or "clinicallysignificant opioid-related adverse reactions intervene."
ACTAVIS0193441	3/5/2013	"Kadian PI Workshop" - "Tolerance is the need for increasing doses of opioids to maintain a defined effect such as analgesia (in the absence of disease progression or other external factors)."
ACTAVIS0192847	3/8/2013	Marketing Presentation - "Numerous marketing surveys of doctors in 2010 and 2012, for example, confirmed Actavis's messaging about Kadian's purported low addiction potential, and that it had less abuse potential than other similar opioids." See also ACTAVIS0361609 12/2010 Marketing.
ALLERGAN_MDL_00992106	3/8/2013	This document touts the dosage flexibility of Kadian. It is flexible because of its BID ("bis in die," which means twice a day) and QD ("quaque die," which means once a day). The

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Bates #	Date	Summary
		dosage can be sprinkled on applesauce and should not be abruptly discontinued for those with a physical dependence on the drug.
ALLERGAN_MDL_00992106	3/8/2013	Kadian Sales Training Presentation - lists the goals of chronic pain management, one of which is "to improve the patient's sense of well-being."
ALLERGAN_MDL_00005223	3/8/2013	Family at ALLERGAN_MDL_00005225 – Actavis slideshow examination of "pain market" - states "there is no strong branded product in our current portfolio to serve as the foundation for the pain franchise" SWOT analysis identifies environment encouraging prescribers to write fewer opioids, proposed rescheduling of Norco as threats, says tamper-resistant products are physicians' #1 wish.
ALLERGAN_MDL_00750772	3/8/2013	AVIS0580066Part of family beginning with email at ACTAVIS0192811 from Leitch to Gallagher re: materials for Sept meeting, most notably sales training and tactics.
ALLERGAN_MDL_00993613	4/25/2013	"The Nervous System" - Appears to be an Actavis speaker presentation. Tolerance and Dependence. Drug loses its effectiveness with repeated use; higher dose required to produce same analgesic effect. Management is to increase dose and/or frequency of administration; Combine opioid and nonopioid to achieve additive analgesia without increasing opioid dose; Slowly taper dose by 10% to 20% every other day to manage physiological dependence. *Confidential for training purposes only.
ACTAVIS1011873	5/9/2013	section 4.3.1 is Call Center Activities showing collection of data from doctor calls Part of hot family re Email to people from several different organization re: REMS team meeting minutes/materials.
ACTAVIS1011873	5/9/2013	Email to people from several different organization re: REMS team meeting minutes/materials. Attachment at ACTAVIS1011900 - Testimonials, in a blog-type platform, discuss adverse events,

Bates #	Date	Summary
		addiction – including with no prior history of abuse, horrible withdrawal/insomnia, dissolving, injecting. Mentions "addiction doc"(tors) in contrast to pain doctors.

Additionally, pursuant to FRCP 33(d), Plaintiff identifies the following documents:

PURCHI-003286781
 PURCHI-003286781
 PURCHI-003286781
 PURCHI-003286781
 ABT-MDL-KY-0001668
 PURCHI-003286781
 PURCHI-003286781
 ABT-MDL-KY-0024177
 CHI_000169914
 PURCHI-003286781
 PURCHI-003286781
 CHI_000169914
 ABT-MDL-KY-0024177
 PPLP004033318
 PURCHI-003286882
 CHI_000169914
 CHI_000169914
 PPLP004030463
 PURCHI-000675080
 PURCHI-000679205
 PURCHI-000675080
 PURCHI-000675080
 CHI_000169914
 PPLP004086124
 PPLP003549472
 PPLP004033318
 PPLP003996972
 PPLP003420538
 PPLP004001344
 PPLP004001344
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 PPLP003344295
 PPLP003344860
 PPLP003344860
 PPLP003344932
 PPLP003420448
 PPLP003461097

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PPLP003420572
 PPLP003420538
 PPLP003420538
 PPLO003461097
 PPLP003420538
 PPLP003409899
 PPLP003409457
 PPLP004001344
 PKY1738102062
 PPLP004033318
 PDD1712900035

Date	Document	Summary
2000	Actiq 2000 Master Plan, (TEVA_CHI_00042757) (Doc. 227).	Actiq master plan noting regulatory oversight as key hurdle in Actiq's success, need to market to pain management specialists who are likely to be aggressive adopters of Actiq, and the weakness of a limited indication and need to expand that indication.
2003	Actiq 2003 Marketing Plan, (TEVA_MDL_A_00454872) (Doc. 229).	2003 marketing plan outlines current market dynamics, SWOT analysis and key marketing issues, the Actiq vision, marketing and promotional strategy, and the core Actiq tactical plan, including target audience.
2004	Actiq 2004 Marketing Plan, (TEVA_MDL_A_00454872) (Doc. 230).	Similar to 2003 marketing plan; outlines current market dynamics, SWOT analysis and key marketing issues, the Actiq vision, marketing and promotional strategy, and the core Actiq tactical plan, including target audience.
4/30/2004	FDA Meeting Minutes FDA Accuses Cephalon of Off Label Promotion, 4/30/2004, (TEVA_MDL_A_00505359) (Doc. 302).	Key document showing FDA accusation against Cephalon regarding use of sales force for off-label marketing (p. 360) and criticism of how they market for break-through pain for non-cancer patient specialties.
2005	Actiq 2005 Marketing Plan, (TEVA_MDL_A_00455000) (231).	2005 Marketing Plan shows that Teva is still actively marketing to non-cancer areas as evidenced by Teva's PDE's (Primary Detail Equivalent), which is a detail that is in the first position (i.e., no other product receives more emphasis or focus) in a sales call by a pharmaceutical sales representative (see Slide 4).

Date	Document	Summary
5/24/3018	Teva Defendants - Responses to Request for Production, 5/24/2018, (TEVA_CHI_00016437) (Doc. 226).	Responses and Objections of Cephalon, Teva, and Actavis to Plaintiffs' First Set of Requests for Production of Documents.
2005	OraVescent Fentanyl (OVF) Commercial Strategy Meeting 2005 PP, (TEVA_MDL_A_00373479) (Doc. 263).	The Commercial Strategy Powerpoint illustrates Teva's approach to commercialization, specifically "creating the need" and selling to that need.
9/26/2005	PMEAB 2005 FEBT Marketing PP, 9/26/2005 (TEVA_MDL_A_00399532) (Doc. 276).	FEBT Marketing Powerpoint shows how Teva continued to market to non-cancer patients.
2006	Pain Medicine 2006 Year-End Report, (TEVA_MDL_A_00564864) (Doc. 285).	2006 Year-End Powerpoint presentation shows Teva had awareness of their off-label marketing and sales practices relating to breakthrough pain, expanding further than their indication for breakthrough cancer pain.
2006	Clinical Management of Breakthrough Pain 2006 PP, (TEVA_MDL_A_00009053) (Doc. 286).	Presentation that encourages market growth by marketing to the symptom (i.e., pain) and not the disease (i.e., cancer) (see Slide 2 and Slide 3).
2006	Actiq 2006 End of Life Cycle Plan, (TEVA_MDL_A_00366691) (Doc. 228).	Discusses end of life-cycle for Actiq due to generic erosion, and outlines key issues and critical success factors for opioid launch after Actiq patent expiration.
2006	Actiq Marketing Executive Committee 2006 Update, (TEVA_MDL_A_00366344) (Doc. 288).	Actiq market committee report from 2006 showing prescription trends, including charts showing that only 7% of prescriptions came from oncology practices (see Slide 8).
8/8/2006	Email re June Ranking Report, 8/8/2006 (TEVA_CHI_00004942) (Doc. 154).	Randy Spokane email discussing June 2006 sales ranking report, and need to continue driving Actiq sales until the day Fentora is launched.

Date	Document	Summary
6/1/2018	Opioid Litigation – Kelsie Konigsberger Report, Former Teva Sales Representative, 6/1/2018, (Doc. 317).	Kelsie Konigsberger was interviewed by Motley Rice, discussing Teva's strategy to market Fentora to pain specialists.

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		<p>Konigsberger states that “20 to 30” percent of oncologists on her REMS target list objected to enrolling in the REMS program; the remainder of doctors were pain specialists who had no qualms about prescribing Fentora.</p> <p>Konigsberger emphasized that “99 percent” or more of the prescriptions of Fentora written in her territory were “off-label” prescriptions issued by pain specialists.</p> <p>Konigsberger recalled that some of the doctors were concerned about abuse and diversion of Fentora. She also recalled that “patients lined up in droves” at some clinics because the doctors were the “top opioid prescribers” and word had gotten around that patients could get Fentora and other opioids from these prescribers.</p> <p>Konigsberger did not know of any instances in which Teva had reported such activity to regulatory authorities.</p>
2006-2011	Ohio Sales Call Run Document, (TEVA_MDL_A_00763717) (Doc. 319).	Approximately 250-page spreadsheet showing detailing calls made in Ohio by Teva Sales representatives, providing product, sales representative name, and health care provider’s name and address.
N/A	Amrix Speciality Code Description Chart, (TEVA_MDL_A_00700492) (Doc. 320).	Spreadsheet providing specialty code descriptions used to categorize physician specialties by sales representatives. Includes non-cancer specialties throughout the spreadsheet.
2006	1st Quarter 2006 Incentive Compensation Plan Memo, (TEVA_CHI_00038512) (Doc. 166).	<p>1st Quarter 2006 Incentive Compensation Plan, detailing sales quotas and target bonuses for sales representatives.</p> <p>Shows that Tier 1 sales representatives will be paid \$0.09 on every dollar of sales generated over the 1st quarter quota up to a maximum payout of \$9,000, and Tier 2 will be paid \$0.07 on every dollar of incremental sales generated above the Tier 1 maximum.</p> <p>The target bonus was \$11,250.</p>

2006	4th Quarter 2006 Incentive Compensation Plan Memo, (TEVA_CHI_00038518) (Doc. 167).	<p>4th Quarter 2006 Incentive Compensation Plan, detailing sales quotas and target bonuses for sales representatives.</p> <p>The target bonus for Fentora launch is \$11,250 based on two components: (1) Fentora retail prescription dollars, DDD non-retail, and DDD mail-order dollars; and (2) Fentora DDD retail pharmacy dollars, DDD non-retail, and DDD mail-order dollars.</p>
3/2013	J Natl Compr Canc "Guidelines for the Management of breakthrough Pain in Patients with Cancer," 3/13, (Doc. 282).	<p>Journal article titled, "Guidelines for the Management of Breakthrough Pain in Patients with Cancer," discussing a comprehensive pain management approach that addresses the various presentations of pain in patients with cancer.</p> <p>Defines breakthrough pain as "transitory exacerbations of pain that occur on a background of stable pain otherwise adequately controlled by around-the-clock opioid therapy."</p> <p>Concludes that all "evidence-based guidelines on managing idiopathic breakthrough pain in cancer include rapid-acting opioids as a treatment option, most of which also include fentanyl formulations."</p> <p>Further notes that it is important "not to overuse rapid-acting opioids for pain that could be managed with around-the-clock opioid titration and with the careful and well-established use of immediate-release oral opioids or other therapeutic strategies."</p>
2006	4th Quarter 2006 Incentive Compensation Plan Memo, (TEVA_CHI_00039257) (Doc. 162).	<p>4th Quarter 2006 Incentive Compensation Plan, detailing sales quotas and target bonuses for sales representatives.</p> <p>States that total Fentora 4th quarter 2006 target bonus is \$12,000, based on 2 components: (1) Fentora retail prescription dollars plus non-retail and mail-order DDD dollars; and (2) Fentora DDD retail pharmacy dollars plus non-retail and mail-order DDD dollars.</p>

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6/2006	June 2006 Pain Care Specialist Ranking Report, 6/2006, (TEVA_CHI_00004943) (Doc. 154).	<p>Email from Randy Spokane attaching June sales ranking report, and also noting the top sales representatives.</p> <p>Notes that as the lifecycle of Actiq begins to near its end, sales representatives must remain focused on driving sales until the day Fentora is launched.</p> <p>Notes that Alex Burlakoff and the Southeast Team finished #1 in Q2. Also recognizes Kelli McKenzie, David Savitt, Lisa Pacin, Karen Hill, Beth Aronica, Sly King, and Matt Morreale as top sales representatives.</p>
2009	3rd Quarter 2009 Incentive Compensation Plan, (TEVA_CHI_00038572) (Doc. 164).	<p>3rd Quarter 2009 Incentive Compensation Plan, detailing sales quotas and target bonuses for sales representatives.</p> <p>States that the target Fentora 3rd quarter bonus is \$2,625. Further explains that "For 3rd quarter 2009, your Sales Base will be the average of 1st quarter 2009 and 2nd quarter 2009. This Sales Base will be used to calculate your Target Quota. If your 3rd quarter 2009 sales equal your Target Quota you will earn the Target Bonus of \$2,625. In addition, you will be paid \$0.5 for every sales dollar you generate over your Target Quota."</p>
2012	2012 Memo re Fentora REMS, (TEVA_CHI_00004423) (Doc. 152).	Memo stating that on "March 13, 2012 the Fentora REMS will officially be locked-down" so there "are only (14) selling days remaining to enroll Health Care Providers (HCPs) AND earn significant bonus for your efforts."
7/1/2012	Fentora Targeting Assessment and Call Activity Document, 7/1/2012, (Doc. 324).	<p>Targeting assessment and call activity memorandum discussing policy details regarding targeting assessments, sales representative call activity, do not compensate (DNC) specialties, one-time calls on DNC specialties, and monitoring.</p> <p>Specifically states that "Teva only promotes its products to those HCPs when it is reasonable to believe that his or her practice includes patients that could be treated with a Teva product for an on-label indication."</p>

		Also states that “[s]ales calls do not include e-mails, text messages, faxes or telephone calls to HCPs.”
7/25/2018	Komal email re Top 100 Prescribers, 7/25/2018, (Doc. 334).	<p>Email identifying Top 100 providers and “do not call” providers.</p> <p>Notable top 2010 prescribers include Louis Spagnoletti, who was temporarily barred from treating patients by NJ’s AG for indiscriminate prescribing, Gordon Freedman, who was indicted for receiving kickbacks, and Charles Brown, a nurse practitioner convicted of conspiracy to distribute opioids including fentanyl at a pill mill.</p>
12/2005	Fentora Marketing Plan 2005-2006, (TEVA_MDL_A_00368405) (Doc. 270).	<p>2005 FEBT (Fentora) marketing plan discussing transition of physicians from Actiq to Fentora. Provides market and competitor assessments, and a SWOT analysis. Also notes critical success factors and key issues.</p> <p>States that key issues include “low understanding of diagnosis and treatment of breakthrough pain (BTP),” “limited KOL, society, and MCO relationships,” and “concern for abuse, addiction, & diversion.”</p> <p>Critical success factors for Fentora include “expand KOL, society & MCO relationships,” “minimize abuse, addiction, & diversion,” and “converting Actiq loyalists within 90 days.”</p> <p>Also discusses the “challenging selling/marketing environment requiring sophistication and expertise.” Specifically notes that “the FDA requires all newly approved schedule II opioid products to implement a comprehensive Risk Minimization Plan” which will “contribute to the difficulty and complexity of selling/marketing a CII medication.”</p> <p>“Another complexity is that the undertreatment of pain continues to be a widespread problem. It has been postulated</p>

		<p>that one reason why pain is undertreated is physician fear of prescribing opioid analgesic medications (i.e., opiophobia). This fear is mostly attributed to concerns of abuse, addiction, and diversion, as well as scrutiny by regulators that monitor the prescribing and dispensing of these medications.”</p> <p>Cites to Portney’s breakthrough pain study, stating “Portney’s BTP survey identified ... that there is a need to study BTP therapies in areas beyond cancer – in particular in back and neuropathic patients” because the “prevalence of cancer-pain patients is significantly less than non-cancer pain patients.”</p> <p>One strategy to minimize risk for abuse, addiction, and diversion was to “negotiate optimal RiskMAP to meet standards and minimum risk without compromising appropriate use and opportunity,” as well as “educate patients about safe use of FEBT and allay fears of opioids.”</p>
	<p>Fentora FAQs and Suggested Responses, (TEVA_MDL_A_00394119) (Doc. 172).</p>	<p>Fentora frequently asked question responses regarding abuse, addiction and diversion and minimizing risks associated with Fentora to properly market.</p> <p>Sales aid states that appropriate patients are:</p> <ul style="list-style-type: none"> • Regularly taking around-the-clock (ATC) opioid regimens to control persistent pain • Considered opioid tolerant • Cancer-related chronic pain • 1 to 4 episodes of BTP per day <p>Also notes that “FENTORA contains fentanyl, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. FENTORA can be abused in a manner similar to other opioid agonists, legal or illicit.”</p>

		<p>“Cephalon believes that a proactive approach to communicating the potential risks of opioid analgesics is a key component of minimizing risks. As a result we have developed a comprehensive 3 primary objectives of the SECURE Program:</p> <ol style="list-style-type: none"> 1. Ensure that patients and healthcare professionals understand that FENTORA should be used only by opioid tolerant patients with cancer 2. Minimize the potential for misuse, abuse and diversion of FENTORA 3. Minimize unintended or accidental exposure to FENTORA”
2006	Fentora 2006 PP "A Change is Coming...Effervescent Speed," (TEVA_CH_00004953) (Doc. 155).	<p>2006 Fentora launch powerpoint. Notes that target audience for Fentora is “healthcare professionals”, and also discusses voucher program (i.e., 75 vouchers per rep for Q4). Also notes that generic opioids are a threat.</p> <p>Slide 16: Provides Fentora’s Clinical Plan, including breakdown of Cancer studies and non-cancer breakthrough pain studies, with publication plans for each.</p> <p>Slide 10: Lists “Direct Selling Tools for Launch” including “Patient FAQ Brochure, Administration Tear Sheet, Medication Guide, Placebos, Patient Starter Kit.”</p>
2006	Oravescent Fentanyl (Fentora) 2006 Pre-Launch and Launch Plan PP, (TEVA_MDL_A_00008300) (Doc. 267).	<p>Fentora pre-launch and launch plan.</p> <p>Slide 14 shows that Cephalon has the opportunity to “[c]hange the perception of BTP and increase awareness for appropriate treatment (RAO).” However, the weakness is that the “[l]abel is limited at launch to BTP in cancer.” And Cephalon notes as a threat to profits “increased regulatory scrutiny and media attention.”</p> <p>Slide 45 discusses “using PR to shape opinion.” In particular, Cephalon wanted to “repair the opioid category image – put the abuse potential into perspective versus “patient abuse” resulting from untreated pain.”</p>

		<p>Slide 33 shows Cephalon's plan to "Expand into Nonmalignant Pain," including "continue to develop clinical evidence supporting broader use of [Fentora]" and "expand investment in the chronic pain management category."</p> <p>Slide 50 shows how Cephalon planned to "ally with employers/unions" and "focus on large, often self-insured, enterprises that employ workers who can be marginalized by BTP," including "construction," "transportation," and "civil service."</p> <p>Discusses how breakthrough pain is "open to interpretation", but must be precisely defined. Cephalon wanted to link "BTP inextricably to unpredictable, rapid & intense BTP."</p>
	GlenGarry Glen Cephalon, (TEVA_MDL_A_00404021) (Doc. 277).	<p>Breakthrough pain and Fentora sales script based off GlenGarry Glen Ross monologue, stating how sales reps need to "close or hit the bricks."</p> <p>"You think they want to write Percocet? The doctors don't prescribe unless you close them. They're sitting out there waiting to give you their money. Are you gonna take it? Are you going to exceed quota?"</p> <p>"These are the Fentora targets. And to you, they're gold."</p> <p>"Man o'Man am I motivated to get out there and sell Fentora!"</p>
2006	Clinical Management of Breakthrough Pain 2006 PP, (TEVA_MDL_A_00009053) (Doc. 286).	<p>2006 Breakthrough Pain PowerPoint presentation.</p> <p>States that "Cancer pain [vs] noncancer pain...Categorization by disease is less important than pain pathophysiology." This PowerPoint presents many patient profiles who are "eligible" for opioid treatment, most of whom are not cancer patients.</p>

		<p>Slide 2 notes that “Noncancer \approx Cancer” and that categorization by disease is less important than pain pathophysiology.</p> <p>Slide 24 reinforces need to minimize risks for abuse, misuse, and diversion.</p> <p>Slide 57 discusses “Barriers of Optimal Opioid Use” including: abuse and addiction concerns; confusion (physical dependence, tolerance, addiction).” It also notes consequences of addressing the limiting factors including: pain undertreated; potential stigmatization despite the legitimate opioid use.</p> <p>Slide 58: All Addicts are Abusers, But Not All Abusers are Addicts</p> <p>Slide 60: Unresolved issues</p> <ul style="list-style-type: none"> – Patient selection – Appropriate dosing – Patient monitoring – Problematic patients <p>Slide 102: Concluding Comments: Cancer and noncancer BTP require similar analgesic approaches; BTP adversely affects QoL and function in cancer and noncancer patients.</p>
8/9/2006	Fentora Launch Planning 2006 Update, (TEVA_CHI_00005721) (Doc. 241)	<p>Fentora Publication Plan showing intent to publish both cancer and non-cancer studies from 2005 to 2007. Also provides summary of marketing priorities for Fentora launch.</p> <p>Notes key accomplishment as publication of Portneoy’s non-cancer breakthrough pain survey published in J Pain.</p> <p>Sets priority for “development of CephalonSpeaker.com website to support Fentora.”</p> <p>Outstanding issue noted is the “finalization of revised RiskMAP for submission to FDA.”</p>

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		Slide 14 discusses use of Fentora for non-malignant chronic pain in opioid-tolerant patients.
9/25/2006	Memo re Cephalon Receiving FDA Approval of Fentora for the Management of Breakthrough Pain in Patients with Cancer, (TEVA_CHI_00005323) (Doc. 156).	Fentora Press Release stating that "Cephalon Receives FDA Approval of FENTORA for the Management of Breakthrough Pain in Patients with Cancer."
2007	"Weighing in on the Off-Label Use of Actiq for Noncancer-Related Pain; A Recipe for Success or a Recipe for Disaster?" 2007, (Doc. 221).	Article regarding off-label Actiq use written by Cephalon Speaker Bureau member. "Our longer-term clinical strategy is focused on developing FENTORA for patients with breakthrough pain associated with other conditions, including neuropathic pain and back pain."
2007	Fentora 2007 Marketing Plan, (TEVA_MDL_A_00398243) (Doc. 264).	2007 Fentora Marketing Plan. "Growth Inhibitors: -scrutiny from regulators and general confusion on the part of key stakeholders fuels concern about the abuse, addiction, and diversion of opioids" "Key environmental trends-Social/cultural: Abuse and diversion are top-of mind topics for physicians and other stakeholders, Political/governmental: Opioid abuse is a hot political issue and physicians are under significant scrutiny about proper use of opioids, FDA is hypersensitive about safety issues" Fears for Physician: Patient abuse, addiction, & diversion of opioids, Regulatory scrutiny. Fear for Patients: Addiction (loss of independence), Over medication (sedated / confused), Running out of opioids (rationing), Anxiety over severity and timing of next breakthrough pain episode (unpredictability), Physicians will stop prescribing opioids. Slide 33: Growth Drivers: Aging baby boomers and growing US population will increase the size of the chronic pain patient

		<p>population; Increase in treatment of chronic pain with opioids; Pain Specialists are more aggressive in treating chronic pain; More sophisticated usage of opioids by PCPs who continue to drive the majority of opioid TRx volume; Increasing understanding about the proper identification, diagnosis and treatment of BTP; New competitive entries</p> <p>Growth Inhibitors: Scrutiny from regulators and general confusion on the part of key stakeholders fuels concern about the abuse, addiction, and diversion of opioids; Due to the widespread availability of generics in the opioid market, managed care has placed significant restrictions on the use of branded opioids; Chronic pain practice standards (especially for BTP) are still evolving; Physicians believe that increasing the dose or dosing frequency of LAOs can adequately cover a BTP episode while ignoring the effects of overmedication [influenced by Purdue and Janssen]; Perception by some physicians that SAOs are a preferred treatment option for BTP based on familiarity, ease-of-use, and cost.</p> <p>Slide 76 notes the Fentora SWOT Analysis:</p> <p>Strengths: Published Data in non-cancer BTP</p> <p>Weaknesses: Limited label (BTP in cancer patients) at launch and potentially up to 3 years post-launch due to carcinogenicity study, perceived safety concerns of fentanyl due to misunderstanding of potency and equianalgesic conversion (mg vs. mcg)</p> <p>Slide 77 continues the Fentora SWOT Analysis:</p> <p>Opportunities: Aging population</p> <p>Threats: Limited understanding of BTP and its appropriate management outside a small</p>
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		<p>community of pain specialists, fear of abuse and diversion with opioids, increasing government restrictions on C-II opioids</p> <p>Slide 80 sets out the FENTORA mission of establishing FENTORA as the gold standard for breakthrough pain.</p> <p>Slide 96 discusses issues and strategies for Fentora.</p> <p>Issue: Risk for abuse, addiction, and diversion</p> <p>Strategies: Educate HCPs on appropriate patient selection, educate patients about safe use of FENTORA and allay fears of opioids, continue to implement risk minimization tools, maximize SECURE outreach program initiatives</p>
2008	Competitive Intelligence 2008 Report, (TEV_FE00002696) (Doc. 236).	2008 Internal memo discussing competitive intelligence priorities, and need to develop competitive blunting strategies.
2008	Fentora 2008 Brand Plan, (TEVA_MDL_A_00370019) (Doc. 290).	<p>2009 Marketing Plan. Examples of distinction between Cancer BTP and Noncancer BTP. Goal is to establish BTP as a disease state. Providers SWOT analysis, and key issues, as well as publications plan and public relations plan (see App. A and B). Slide 33: Notes key environmental trends-Social/cultural. States that “[a]buse and diversion are top-of mind topics for physicians and other stakeholders. Also notes key political/governmental trends including “opioid abuse is a hot political issue and physicians are under significant scrutiny about proper use of opioids; FDA is hypersensitive about safety issues.”</p> <p>Slide 35: Growth Drivers: Aging baby boomers and growing US population will increase the size of the chronic pain patient population; Increase in treatment of chronic pain with opioids; Pain Specialists are more aggressive in treating chronic pain; More sophisticated usage of opioids by PCPs who</p>

		<p>continue to drive the majority of opioid TRx volume; Increasing understanding about the proper identification, diagnosis and treatment of BTP; New competitive entries.</p> <p>Slide 83: Put forward Fentora SWOT Analysis:</p> <p>Strengths: Published Data in non-cancer BTP</p> <p>Weaknesses: Limited label (BTP in cancer patients) at launch and potentially up to 3 years post-launch due to carcinogenicity study, Perceived safety concerns of fentanyl due to misunderstanding of potency and equianalgesic conversion (mg vs. mcg)</p> <p>Slide 84: Fentora SWOT Analysis:</p> <p>Opportunities: Aging population</p> <p>Threats: Limited understanding of BTP and its appropriate management outside a small community of pain specialists, fear of abuse and diversion with opioids, Increasing government restrictions on C-II opioids</p>
7/2/2008	Fentora 2008 Marketing Overview PP for Megaffin, 7/2/2008, (TEVA_MDL_A_0037524) (Doc. 271).	<p>2008 Fentora Marketing Powerpoint.</p> <p>Slide 7 shows chronic pain prevalence, diagnosed and treated by underlying conditions. Cancer has the lowest prevalence, lowest diagnosis, and lowest treatment. Meanwhile, arthritic pain is the highest, with neuropathic pain a close second. Back pain is third, but represents approximately 9 million more patients than cancer pain.</p> <p>Slide 22 shows graph with back pain as the most treated condition with Actiq, followed by neuro, headache, cancer, and arthritis. Back pain represented 38% of underlying conditions treated with Actiq.</p> <p>Slide 34 shows Fentora's "potential for abuse" as a barrier based on physician</p>

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		<p>perceptions, and that it is a “potent opioid (held in reserve).”</p> <p>Slide 36: “Threats: Risk for abuse and diversion...Critical success factor: Minimize risk for abuse and diversion”</p> <p>Slide 41 shows a bar graph illustrating the percentage of underlying conditions treated with Fentora. Cancer represents only 18%, while back pain is 20%, neuro is 12%, and other pain is 27%.</p>
7/11/2008	Fentora Critical Success Factors (CSF), 7/11/2008, (TEVA_MDL_A_00376298) (Doc. 157).	<p>2008 Fentora Marketing Powerpoint discussing Fentora's critical success factors.</p> <p>The highest rated issue facing Fentora is “Achieving broad acceptance of BTP (breakthrough cancer pain) (both CA and non-CA) and need for ROO (rapid-onset opioid) solution in light of broad array of LAO/SAO options.”</p> <p>Another key issue for Fentora is the “perception of increased risk of abuse with ROO (rapid-onset opioids) products.”</p> <p>Included on Fentora’s list of critical success factors are: “greater awareness of BTP & acceptance of ROO,” “clear & consistent communication of Fentora risks,” “differentiated from competitors,” and “patients have access to reimbursement similar to Actiq at peak.”</p> <p>One of the key strategies for differentiating Fentora was to “successfully bring to market a non-CA BTP indication.”</p> <p>Cephalon also planned to “use the non-ca label expansion to accelerate awareness and trial,” and also “secure better support from pain societies.”</p> <p>With regard to the key issue of risk for abuse, addiction, and diversion, Cephalon states “TBD.”</p>

		<p>"Issue: Physicians and patients have limited understanding about the appropriate diagnosis and treatment of BTP; Critical Success Factor: Physicians and patients have a greater awareness of BTP and accept ROOs as ideal treatment; Strategies: Develop an unbranded disease state awareness campaign focused on CA BTP, which could efficiently evolve into a broader BTP campaign upon securing a label expansion. Bridge the communication gap between patients and physicians by creating a common language. Develop a burden of illness story to strengthen the need/importance of effectively addressing BTP"</p>
2009	Fentora 2009 Brand Plan, (TEVA_MDL_A_00398245)(Doc. 275).	<p>2009 Fentora Brand Plan.</p> <p>"One barrier to successful management of chronic pain with opioids is concern associated with abuse, addiction, and diversion."</p> <p>"Market drivers: Increase in number of chronic pain patients continues to drive opioid sales. Market Threats: Concern persists for abuse, addiction, and diversion."</p> <p>Cephalon noted key challenges with their RiskMAP, SECURE, including "15% to 40% of patients on Fentora may not meet the strict definition of opioid tolerance defined in the label," "sales force will be integral in driving enrollment and participation," and "approval of the expanded label is contingent on documenting the effectiveness" of the RiskMAP</p> <p>Cephalon sought to "obtain expanded label after REMS [was] shown to be effective," as well as "[s]ubmit high dose after REMS [was] shown to be effective."</p>
2010	Fentora 2010 Program Review/Website Promotions, (TEV_FE00030646) (Doc. 237).	2010 extensive summary of marketing material for Fentora.

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		<p>Includes PDR sponsorship, specifically sponsorship of the 2010 Pain Management Prescribing Guide.</p> <p>Cephalon conducted a breakthrough pain workshop for pain management specialists.</p> <p>Also includes payment stubs from shareyourpain.com -- a support website for those with severe pain and other online tools such as a "digital pain tracker" where patients can record frequency of pain to show their doctor.</p> <p>Cephalon also provided nurse counseling kits designed to help them educate patients on breakthrough pain, Fentora, and the SECURE (RiskMAP) program.</p>
2009	Fentora 2009 Brand Plan, (TEV_FE00037945)(Doc. 240).	<p>2009 Fentora Brand Plan.</p> <p>Situation Analysis, marketing strategy, and marketing expenses.</p> <p>Provides summary of key 2008 market issues (i.e., limited understanding of breakthrough pain) and 2008 key strategic imperatives (i.e., greater acceptance of breakthrough pain).</p> <p>The brand plan also provides the 2008 Fentora expense budget, which includes a total budget of \$15,175,000, with 5.75 million allocated for advertising promotional materials, 2.7 million allocated for field driven speaker programs, 1.8 million allocated for medical education, 1.3 million for meetings, conferences, Congresses, conventions, and exhibits, and 1.2 million allocated for samples and debit card program.</p> <p>2009 challenges for Fentora include "REMS/Registry logistics," "reimbursement hurdles," and "concerns for abuse misuse, and diversion."</p>

		<p>Page 28: Outlines opportunities, including: Aging Population; Lists threats as “safety concerns for abuse and diversion.”</p> <p>The 2009 sales goal was \$175m total revenue, and 76,334 TRx’s.</p>
2010	Fentora 2010 Brand Plan, (TEV_FE00030805) (Doc. 238).	<p>2010 Fentora Brand Plan.</p> <p>Discusses need to optimize BTP treatment, particularly with rapid-onset opioids, such as Fentora.</p> <p>States that there is “limited opioid REMS awareness, acceptance and endorsement by HCPs.” The “prescriber base is not REMS savvy” and there is a “perception of increased burden to HCP and office staff.”</p> <p>Cephalon wanted “to see Fentora considered earlier in the treatment algorithm” because “ROOs (rapid-onset opioids) are considered only after” LAOs or SAOs.</p> <p>2010 key promotional tactics include “ShareYourPain.org” and “unbranded website to educate patients on the components of chronic pain.”</p>
2011	Fentora 2011 Brand Plan, (TEVA_MDL_A_00556008) (Doc. 279).	<p>2011 Fentora Brand Plan.</p> <p>“Strengths: Precise/Not over-medicating; Flexibility to re-dose/Delivery matches pain; Fast and powerful; Reliable and predictable; Permits patient functionality; Bright future - Pipeline; Heritage - Well-studied/Proven; REMS as safety net...Weaknesses: Expensive/Lack of coverage - weak Cost vs. Value perception; REMS is viewed as a hassle; Misunderstood - across all stakeholders; Limited peer influence - HCPs and patients; Lack of consistent messaging or sales force focus (e.g. “BTCP” vs. “BTP”); Low awareness.”</p> <p>“Rebranding Fentora from Illness to Wellness: Concept: Expand upon and continue to refine the FENTORA brand story</p>

		<p>to focus on successful treatment outcomes framed within patient functionality.”</p> <p>Slide 11: Objective: Reinforce knowledge about BTP identification and evolve messaging from treatment matching to regaining/maintaining functional goals</p> <p>Slide 13: Objective: To increase HCP acceptance and awareness of BTP</p>
2/17/2011	“Deaths From Prescription Pain Killers Still Rising,” 2/17/2011, (Doc. 114).	<p>Article discussing deaths from prescription painkillers and the opioid abuse epidemic.</p> <p>“The rise in abuse of and deaths from prescription opioid narcotics has reached epidemic proportions, government officials said today during a CDC event for physicians. There were more than 27,000 deaths from prescription drug overdoses in 2007, a number that has risen five-fold since 1990, according to data the agency presented during its latest “Grand Rounds” discussion, which features different public health topics. “Just about the only mortality statistic that is getting worse is death from prescription opioid abuse,” said CDC director Thomas Frieden, MD, MPH, referring to a comprehensive report on the nation’s health released yesterday that showed declining mortality rates for all other conditions, including heart disease and cancer.”</p>
12/8/2011	“Teva’s Cephalon Wins Appeal Against Watson Over Fentora Copy”, 12/8/2011, (Doc. 117).	<p>Article regarding Fentora Sales only 160m, but Cephalon wins patent protection for Fentora until 2019.</p> <p>Teva Pharmaceutical Industries Ltd.’s Cephalon unit won an appeals court decision that prevents Watson Pharmaceuticals Inc. from selling a generic copy of the painkiller Fentora until 2019.</p>

Endo was an active presence in the pain landscape well before the launch of Opana ER. Endo had established ties with major pain organizations, both in conjunction with its products in the opioid sphere, as well as other pain products, like Lidoderm. In 2001, Endo boasted that it had

“leveraged our brand equity to gain recognition amongst the pain community”. ENDO-OPIOID_MDL-02740220. Its Pain Management Expertise developed a “focused sales force and clinical education effort with: thorough knowledge of the pain management effort” and “well-established customer relationships with the pain management community and thought leaders.” *Id.*

Endo developed a “pyramid of influence, where it spelled out the purpose of these relationships.” *Id.* The pyramid illustrated the correlation between the amount of focus Endo would apportion to the various targeted groups and the resulting influence each category would yield. Endo would focus, in order of importance from least to greatest, on community prescribers, local advocates, regional opinion leaders and finally, national thought leaders. *Id.* In turn, the influence wielded by those at the top of the pyramid, the national thought leaders, would flow down to widening groups of regional opinion leaders and local advocates until it reached the largest group, community prescribers. *Id.* Endo recognized that developing relationships, peer influence and information could lead to a “competitive advantage for Endo” as well as “expanded use of current and future products.” ENDO-OPIOID_MDL-02344002.

Further, there had also concerns about the abuse liability of Percocet, one of Endo’s most successful products. ENDO-CHI_LIT-00543481. To prepare the brand team for challenges to Opana, Endo hired crisis management company, Waggener Edstrom, and formed an Issues Management team to develop a crisis response plan for Opana ER. ENDO-CHI_LIT-00543507. Endo’s concern was that “Misuse/Abuse risk perception may create negative environment and a PR crisis for OxyM and Endo pain franchise”. ENDO-CHI_LIT-00543508. The goals of the crisis response included creating “supportive public policy environment for OxyM and C-II pipeline”, fostering “responsible balance of legitimate patient access and risk management”, and inoculating “against a PR crisis.” *Id.* Internal documents compared this preparation to “Buying insurance”, and rationalized that “While there is no certainty that Endo will face the same kind of crisis in the

commercialization of OxyM, we shouldn't assume that we won't." ENDO-CHI_LIT00543498. The Issues Management team recommended that Endo "'buy insurance' by investing time and energy now in preparing for a potential crisis so that potential harm may be minimized." *Id.*

Opana's 2007-2011 Business Plan included a strategy to "educate [health care providers] and payers on the role of opioids in pain management and their appropriate use and how Opana fits into this paradigm." By doing so, it would help Opana "gain entrée via perceived unmet need." ENDO-CHI_LIT 00545916.

The 2007-2011 business plan outlined strategies Opana could use to penetrate the market, including: 1) Differentiating Opana brand based on efficacy and dosing advantages; 2) Educating health care providers ("HCP") and payers on the role of opioids in pain management and their appropriate use and how Opana fits into this paradigm; 3) aggressively contracting with third party payers to gain and maintain required access; and 4) focusing Opana's resource deployment in order to penetrate market on as narrow a front as possible. *Id.* Each of these strategies would be executed by emphasizing the core messages of the brand. Opana ER's core messages were its "proven 12 hour dosing", its unique pharmacological profile that offered no known CYP450 drug-drug interaction effect, higher potency than oxycodone, low fluctuations between peak to trough plasma concentrations, long half-life, and lastly, its rapid relief due to max plasma concentration peaks within 30 minutes of oral administration. *Id.* Endo also positioned Opana ER as a good option for an opioid rotation regimen and touted the ease of using the FDA approved conversion chart from other opioids to Opana ER. *Id.* Lastly, Opana ER was promoted as one item in a continuum of care that included Opana IR for the relief of breakthrough and acute pain. *Id.* ENDO-CHI_LIT-00547253.

Endo identified a target audience of 950,000 medical care professionals, comprised of primary care physicians, specialists, nurses, nurse practitioners and physicians' assistants. ENDO-

CHI_LIT-00547128. In its 2007 Single-Strategy Plan, Endo further drilled down into the target market, categorizing the various healthcare providers according to their willingness to consider prescribing opioids or whether they were already prescribing opioids. The most promising target segment was the “New Treatment Enthusiasts”, comprised primarily of pain specialists. ENDO-CHI_LIT-00017403. This group alone accounted for 51% of the total prescriptions. *Id.*

As Opana ER progressed beyond the launch period, it continued to develop its core messages. In 2008, Endo unveiled a new message to alleviate doctors’ concerns with prescribing opioids for patients with moderate to severe pain. In March 2008, a National Advisory Board of 23 experts convened by Endo to discuss the treatment of pain and the Opana brand suggested that Endo emphasize Opana ER’s ability to simplify pain treatment. ENDO-CHI_LIT-00190053. The board recommended that the sales and marketing teams highlight the ability of Opana ER to simplify pain treatment and “do nothing to associate Opana ER with complexity of treatment of pain with opioids.” *Id.* Sales representatives and product detail aids should focus on a “simple story for Opana.” *Id.* Endo incorporated this information and other market research into an ad that asked, “Managing the complexities of Pain? Think Opana ER.” ENDO-CHI_LIT-00023299. The 2008 Opana Brand Situation Analysis noted that “PCPs preferred hearing that the agent they selected for treatment would be less risky and therefore, easier for them; they reported a sense of calm after reading the ‘simple’ statement.” *Id.* The 2009 Brand plan indicated that the brand would “continue to position Opana ER as the less complex choice for healthcare professionals in managing moderate to severe chronic pain patients.” EPI001514810.

Endo’s marketing materials suggested that treatment with Opana ER would improve patient’s everyday life, not just relieve pain. The 2006-2010 Business Plan’s positioning statement framed Opana as “the preferred opioid that provided predictable, long-term relief across the widest spectrum of chronic pain conditions to make a real difference in everyday life.” ENDO-CHI_LIT-

00552969. The goal of the creative platform was to convince patients that “Life is better with Opana”, relying on emotional, and unproven, benefits like comfort, predictability, functionality and shift of focus from a patient’s pain to other aspects of their life. *Id.*

Endo integrated “quality of life” and “functionality” claims into a series of branded promotional materials released from 2007 through 2012. In one piece, “Bill the construction worker” is identified as a construction worker dependent on work to support his family. ENDO-CHI_LIT-00033952. His treatment was for moderate to severe lower back pain. *Id.* The materials note that his physician determined that Bill can appropriately use Opana ER for “continuous, around-the-clock opioid therapy.” *Id.* Two patient profiles, released in 2011, “This is Frank” and “This is Ray”, also featured similar patients who needed Opana in order to function in their everyday life. ENDO-CHI_LIT-00099937; ENDO-CHI_LIT-00120586. The patient featured in “This is Frank” had a complicated medical history and was taking several other medications. ENDO-CHI_LIT-00099937. Further, by highlighting the complicated medical history, Endo linked the material back to an Opana core message concerning lack of drug-drug interaction between Opana ER and other medications. *Id.* In a 2012 variation, Endo similarly combined its functional improvement claim with its core message of proven 12 hour relief. “Janice the Chef” suffered from chronic low back pain and needed relief that “lasts a full 12 hours.” ENDO-CHI_LIT-00354604.

The brand positioning statement and the subsequent branded materials did not reveal the lack of data substantiating these claims. The 2008 Opana ER Brand Situational Analysis noted concerns that Opana ER “offered equal or less effective pain relief than competing drugs”, “clinical practice has not substantiated efficacy claims made in marketing materials”, and that it was “not effective for severe chronic pain.” ENDO-CHI_LIT-00023299. Five years later, similar concerns were raised in a 2012 Strategic Platform. Endo identified data gaps where additional data was

needed to support Opana ER aspirational messages. It noted the need for a “proof-of-concept study analyzing productivity and ability of patients to work.” ENDO-CHI_LIT-00467546. Endo further identified a need for “additional data showing the effects of Opana ER on cognitive impairment and judgment, combined with improvements in functionality and sleep, all lead to the best treatment experience for patients.” *Id.*

In addition to branded materials, Endo regularly produced disease state awareness materials discussing chronic pain, pain management and treatment with opioids. The materials listed below demonstrate an effort to reach patients with messages on chronic pain treatment and opioid therapy. A sampling of materials demonstrates disease state awareness efforts beginning as early as 2004. Such materials include:

1. 2004-“Understanding Your Pain”, patient directed material. ENDO-CHI_LIT-00237187.
 - a. “Addicts take opioids for other reasons such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not an addiction.” *Id.*
 - b. “How can I be sure I’m not addicted? Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don’t need it for pain maybe just to escape from your problems. Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons- to relieve your pain and improve your function. You are not addicted.” *Id.*
 - c. “Addiction IS NOT when a person develops ‘withdrawal’ (such as abdominal cramping or sweating) after the medicine is stopped quickly or the dose is reduced by a large amount. Your doctor will avoid stopping your medication suddenly by slowly reducing the amount of opioid you take before the medicine is completely stopped.” *Id.*
 - d. “Addiction also **IS NOT** what happens when some people taking opioids need to take a higher dose after a period of time in order for it to continue to relieve their pain. This normal ‘tolerance’ to opioid medications doesn’t affect everyone who takes them and does not, by itself, imply addiction. If tolerance does occur, it does not mean you will ‘run out’ of pain relief. Your dose can be adjusted or another medicine can be prescribed.” *Id.*

- e. "If you have taken opioid regularly for longer than a week, don't suddenly stop taking it. When your therapy is complete, your doctor will slowly decrease your dose safely." *Id.*
 - f. "If I take the Opioid Now, Will it Work Later When I Really Need It? – Some patients with chronic pain worry about this, but it is not a problem: The dose can be increased or other medicines can be added, you won't 'run out' of pain relief." *Id.*
2. 2008-"Taking a Long-Acting Opioid: What Does It Mean to Me", patient directed material. ENDO-CHI_LIT-00024520.
- a. "Addiction is defined as compulsive drug seeking that is beyond a person's voluntary control even if it may cause harm. Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted." *Id.*
 - b. "If you take an opioid regularly for longer than a week, don't suddenly stop, or decrease the dose by a large amount, because 'withdrawal' symptoms such as abdominal cramping or sweating can occur. When you no longer need this medicine, your healthcare provider will slowly decrease your dose safely." *Id.*
 - c. "Some people taking opioids may need to take a higher dose after a period of time in order to continue to have relief from their pain. This is a 'tolerance' to opioid medications that doesn't affect everyone who takes them, and does **NOT** mean addiction. If tolerance develops, it does not mean you will 'run out' of pain relief. Your healthcare provider can adjust your dose or prescribe another medicine." *Id.*
3. 2009- Caregiver Booklet. ENDO-CHI_LIT-00541211.
- a. "Addiction is defined as compulsive drug seeking that is beyond a person's voluntary control even if it may cause harm. Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted." *Id.*
 - b. "Most healthcare providers who treat people with pain agree that most people do not develop an addiction problem." *Id.*
 - c. "Withdrawal is not pleasant but does not harm the person. To avoid withdrawal problems, it is important to work with their healthcare provider to gradually reduce the dosage." *Id.*
 - d. "Chronic pain can be difficult to treat. It may require combinations of different medicines or the use of strong pain medicines called opioids. The goal of treating chronic pain is to give the sufferer as much relief from pain as possible while letting them continue to function as much as possible." *Id.*

- e. "If tolerance develops, it does not mean you will 'run out' of pain relief. Your healthcare provider can adjust your dose or prescribe another medicine." *Id.*
4. 2009- Taking Long-Acting Opioids/Caregiver Guide. END00442270.
- a. "Most health care providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted." *Id.*
 - b. "Most health care providers who treat patients with pain agree that most people do not develop an addiction problem." *Id.*
 - c. "Physical dependence, which is different from addiction, may develop when taking opioids for pain relief for a long time. This means that your body adapts to the drug and you will have withdrawal symptoms if the medicine is stopped or decreased suddenly. Taking opioids for pain relief is not addiction." *Id.*
 - d. "When someone takes an opioid for a while, they develop a physical dependence on it. If the medicine is stopped suddenly, the person may show signs of withdrawal, such as vomiting and shivering. Withdrawal is not pleasant but does not harm the person. To avoid withdrawal problems, it is important to work with their healthcare provider to gradually reduce the dosage." *Id.*
 - e. "If tolerance develops, it does not mean you will 'run out' of pain relief. Your healthcare provider can adjust your dose or prescribe another medicine." *Id.*
5. 2012- What you should know about treating your pain with opioids. ENDO-CHI_LIT-00277265.
- a. "Symptoms of withdrawal can be avoided by slowly decreasing your opioid dose under the supervision of your doctor." *Id.*
 - b. "Just because you develop withdrawal symptoms if you miss a dose does not mean that you are addicted." *Id.*
 - c. "The risk of becoming addicted to your opioid medicine is reduced if you take your medicine exactly as prescribed by your healthcare provider." *Id.*
6. 2012- Managing Pain with Opioids: Knowing the Facts. EPI002371945.
7. 2014- What you should know about treating Your Pain with Opioids. ENDO-CHI_LIT-00549936.
- a. "Who may be at greater risk for addiction? - Addiction and abuse are more likely to happen if you smoke, already have a drug or alcohol problem, or if you have used illegal drugs in the past. If you have abused alcohol or drugs in the past, you may need to work with an addiction specialist while being treated with opioid medicine. Your healthcare provider can recommend an addiction specialist to help you manage the use of opioids to relieve your pain." *Id.*

- b. "Symptoms of withdrawal can be avoided by slowly decreasing your opioid dose under the supervision of your health care provider. You should not change your dose on your own. Speak with your healthcare provider if you feel that you need to have your medicine adjusted." *Id.*
- c. "Help is available if you need more relief - You may find over time that your medicine is not working as well to relieve your pain as when you first started taking it. This may be because your body has built up a tolerance to the medicine. . . . If you need more pain relief are having trouble sleeping, or are feeling depressed, tell your health care provider. Treatments may be available but a healthcare provider must always be the one to add medicine, change a prescription or adjust the dose. Medication may be one part of the solution." *Id.*

In anticipation of the initial approval date of 2003, Endo earmarked funds for a budget in support of the launch of Opana and Opana ER. The following year Endo received an approvable letter, indefinitely delaying the launch of Opana ER. ENDO-OPIOID_MDL-00279539. The funds were redirected that year with incremental funding resuming in 2004. The total advertising and promotional budget jumped significantly in 2006, the year that Opana ER received FDA approval. ENDO-CHI_LIT-00552982. Below is a chart outlining the advertising and promotional expenditures from 2002 through 2017.

A&P Marketing budget for Opana Franchise		
YEAR	TOTAL	BATES BEG
2002	\$2,000,000	END00001522* ⁷
2003		
2004	\$2,280,000	ENDO-OPIOID_MDL-02149982
2005	\$1,691,000	ENDO-OPIOID_MDL-02149982
2006	\$18,027,000	END00000923
2007	\$19,758,404	EPI000560276
2008	\$25,279,282	EPI000560276
2009	\$17,756,000	EPI001474537
2010	\$15,332,000	EPI001474537

⁷ Annual budget includes Market Research Spending.

2011	\$15,130,000	ENDO-CHI_LIT-00439415
2012	\$19,540,000	ENDO-CHI_LIT-00439415
2013	\$21,650,000	ENDO-CHI_LIT-00439415
2014	\$1,603,870	ENDO-CHI_LIT-00549855
2015	\$750,000	ENDO-CHI_LIT-00549855
2016	\$1,500,000	ENDO-CHI_LIT-00551619
2017		

Training materials utilized by the sales representatives taught specific topics, like low back pain in patients. EPI001554204. These modules gave a comprehensive overview of potential conditions that might necessitate treatment with Opioids, yet they downplayed the risks that opioid medication itself posed. In the low back pain training module, sales representatives learned that “there is a potential for addiction, although this may be less than commonly believed when these medications are used for pain relief.” EPI001554204. It further noted that “[w]hen prescribed properly the use of opioids for chronic pain can be, in some cases, safer than ongoing use of NSAIDS.” *Id.*

Sales reps were also coached on concepts like pseudo addiction. A 2006 training manual on the Oxymorphone Risk Management Plan defined pseudo addiction as “an iatrogenic phenomenon in which a patient with undertreated pain is perceived by healthcare professionals to exhibit behaviors similar to those seen in addiction but is not truly addicted.” ENDO-CHI_LIT-00053284. The manual noted that “physicians can differentiate addiction from pseudo addiction by speaking to the patient about his/her pain and increasing the patient’s opioid dose to increase pain relief.” *Id.* It offered further reassurance that “[p]seudoaddictive behaviors such as clock watching (counting down the time until the next dose) will resolve when the pain is properly treated. [AAPM, 2001, 3].” *Id.*

The manual also downplayed and mischaracterized the risk of physical dependence, comparing physical dependence on opioids to “chronic use of many types of drugs, including many that are not associated with addiction or abuse (such as beta blockers for high blood pressure).” *Id.* Physical dependence was further positioned as an alternative to addiction and explained in the following manner:

[p]hysical dependence can be mistaken for addiction, because in some cases a patient may insist on continued use of the opioid even when pain has resolved, to avoid withdrawal symptoms experience when they try to stop. [AAPM, 2001, 3]. Withdrawal symptoms can be avoided or managed by carefully-tapering off the dose once pain relief is achieved. *Id.*

Tolerance to a drug was also offered as an alternative explanation for drug-seeking behavior. Defined as “the body trying to overcome the effects of the drug”, the manual cautioned “[t]olerance can be mistaken for addiction because the patient may ask for increasing doses of the opioid, which can be perceived as ‘drug-seeking behavior’.” *Id.* The section concluded:

the presence of physical dependence and/or tolerance is not sufficient to state that a person is addicted. Patients treated with prolonged opioid therapy do not usually develop addictive disorders, though the actual risk is unknown and likely varies with genetic disposition, among other factors. [AAPM, 2001, 2] *Id.*

The manual reassured that addiction was different from tolerance and dependence as,

[a]ddiction is a disorder and not an expected consequence of taking an opioid. By contrast, tolerance and physical dependence are expected physical phenomena associated with opioid use. [AAPM, 2001, 3] Tolerance and physical dependence can be mistaken for addiction so the physician must pay close attention to distinguish them from each other. *Id.*

Below is a table summarizing frequent issues covered by the District Managers in the Coaching Reports to their sales team members.

Message	Date	Region	Bates
Frequency of Calls			

Message	Date	Region	Bates
You've made 30 calls on your Fab 5 from Nov 1 to Nov 25, that's about 5 calls apiece. Keep that focus on those 5 docs.	12/5/2006	North Albuquerque, NM	ENDO-OPIOID_MDL-00679355
Hyper Target 5 Top Key physicians 2= times per week (the Fab 5)	12/6/2006	Arlington, TX	ENDO-OPIOID_MDL-00679353
I would like to see you push your prescribers a bit more for real answers. Dr. Van Ginkel has been promising you to write for over a year. He is decile 9 and has not really written Opana considering you have been in his office 25 times this year and have over 80 total calls logged in with him,	4/3/2008	South Miami, FL	ENDO-CHI_LIT-00078382
Insure you are achieving a high frequency of calls against your top 10 OPANA ER targets- minimum 1 calls a week and 2 calls a week against your top 5 prescribers.	12/18/2006	Rome, GA	ENDO-OPIOID_MDL-00680289
Detailing – use of funds			
You have spent your DME on your fab 5 with good focus (Dr. Black, coffee each Monday; lunches with the others) keep that up.	12/5/2006	North Albuquerque, NM	ENDO-OPIOID_MDL-00679355
You got two of your top Opana ER docs and one good potential Opana ER doc on an Opana ER conference call by bringing dinner to their offices... that's outstanding!	12/5/2006	North Albuquerque, NM	ENDO-OPIOID_MDL-00679355
With Dr. Baresh, our lunch centered around managed	2/17/2007	Dayton, OH	ENDO-CHI_LIT-00045831

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Message	Date	Region	Bates
care (which was VERY helpful to understanding the recent changes) and did spend time with a clinical discussion around the benefits of Opana ER for opioid therapy.			
Always demonstrates effective use of DME funds to promote access, build rapport and extend dialogue... You are the top spender...but also the most effective	8/21/2008	Chillicothe, OH	ENDO-OPIOID_MDL-00786258
Efficacy			
The message was good today. I heard "Durable Efficacy" and Dosing advantages" on all Opana calls. Make sure to take the time to give a clear explanation of what they mean as you did with Dr. Barnard.	12/5/2006	North Albuquerque, NM	ENDO-OPIOID_MDL-00679355.
Make sure to take the time and get conversation going on Durable Efficacy and Dosing Advantages. Like we talked about w/ Dr. Roach, focus the BENEFITS of those features on what's important to them (his case was ways that DE and DA could help him deal with his fears of addiction (predictable dosing and limited dose increases).	12/6/2006	Arlington, TX	ENDO-OPIOID_MDL-00679353
Talk about dosing in general and the importance and pitfalls. With durable efficacy talk about tolerance, dose increasing	5/25/2007	North Albuquerque, NM	ENDO-OPIOID_MDL-00684008

Message	Date	Region	Bates
with chronic pain and some of the problems with the overuse of rescue meds.			
You did a good job of presenting Opana ER while addressing questions about abuse, conversion and efficacy from the NPs. I agree that a roundtable would be extremely beneficial in this office.	10/24/2007	Hattiesburg, MS	ENDO-OPIOID_MDL-00688336
"Stay ahead of the pain", being "released from the grip of pain" are taglines that stand out and should be used along with the MVA. These types of statements combined with a thorough and compelling message should help your docs remember Opana better.	10/2/2006	Huntsville, AL	ENDO-OPIOID_MDL-00678060
DM suggestions for messaging "I want to insure(sic) I am properly presenting OPANA ER to insure(sic) that your patients have the chance to try this new medication- I believe in my hear(sic) that some of these patients will have profound and life changing improvement"	12/18/2006	Rome, GA	ENDO-OPIOID_MDL-00680289
DM suggestions for messaging "Doctor wouldn't you agree that OPANA ER's true Q12 dosing and limited need rescue meds will lead to better pain control and allow you(sic) patients to	2/6/2007	South Jacksonville, FL	ENDO-OPIOID_MDL-00686202 at *03.

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Message	Date	Region	Bates
confidently return to a more active life?"			
Minimization of Risk			
Responds to objections and questions by repositioning product and highlighting benefits.	2/17/2001	Dayton, OH	ENDO-CHI_LIT-00045831
Building upon out previous ride along we need to help the physician in identifying the unique needs they and their patients have in chronic pain management and how OPANA ER provides an effective and potentially safer solution,	12/18/2006	Rome, GA	ENDO-OPIOID_MDL-00680289
Reinforce patients studied >2,500 side effect profile similar to other opioids ad well tolerated once properly titrated, the only strong opioid that does not interfere with the CYP 450 system (piece of mind for you and the patient), does not dose dump, low level of undesired side effects <1% of patients report euphoric mood in clinical trials. Safe to use on both opioid experienced and opioid naïve patients.	12/18/2006	Rome, GA	ENDO-OPIOID_MDL-00680289
Sales rep directed to "Read the Avoiding Opioid Abuse book...practice and time is what is needed at this time along with a greater understanding of the Opioid market and the disease state along with more- in depth comfort and	10/20/2008	West Toledo, OH	ENDO-OPIOID_MDL-00700292

Message	Date	Region	Bates
knowledge associated with Opana ER.			
Comparison to other Opioids			
How are you different from Oxycontin was the one that we heard most. Good answers to that. CYP 450, true Q 12, extensively studied, etc.	8/22/2006	North Albuquerque, NM	ENDO-OPIOID_MDL-00677219
You asked some good questions to uncover needs. "How many rescue meds do your patients take, how many is too many? Do they take too many oxy ER?"	5/23/2007	North Albuquerque, NM	ENDO-OPIOID_MDL-00684008
We reviewed your top Oxycontin writers, You should live with these people weekly to get them to write Opana. This is the low hanging fruit that is paying dividends for your counterparts.	10/2/2006	Huntsville, AL	ENDO-OPIOID_MDL-00678060
You were able to get the physician to share with you a patient he has that would benefit from OPANA ER therapy! The patient was on Oxycontin and was using a large quantity of PRN medications and you effectively used your MVA to and the opioid experienced patient data to deliver a key benefit of OPANA ER therapy- fewer occasions for PRN meds because of its true Q12 dosing and durability of effect.	2/6/2007	South Jacksonville, FL	ENDO-OPIOID_MDL-00686202 at *03
Local speaker program promotion			

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Message	Date	Region	Bates
You have 3 of your Fab 5 scheduled to go to the Opana ER Speakers program... THAT's OUTSTANDING!!! I guarantee that this will help your business grow!	12/6/2006	Arlington, TX	ENDO-OPIOID_MDL-00679353.
CEDRIC push the upcoming dinner program in you have in Jacksonville with Dr. Argoff on March 19 th . This is a great opportunity to get your Fab 5 doctors in front of a national thought leader and stimulate utilization of OPANA ER.	2/6/2007	South Jacksonville, FL	ENDO-OPIOID_MDL-00686202 at *04

Manufacturer	Deponent	Deposition Cite
Allergan	Julie Snyder	271:5-24; 272:1-3
Endo	Ronald Perry Wickline	196:3-8; 197:6-25
Janssen	Kimberly Deem-Eshleman	55:9-15; 129:1-15
Purdue	Phil Cramer (30)(b)(6)	Cramer 170:10-25; 171-1-10
Teva	John Hassler (30)(b)(6)	275:14-24;276:1-5
Cephalon (aquired by Teva)	John Hassler (30)(b)(6)	275:14-24;276:1-5
Activas (subsidy of Teva)	John Hassler (30)(b)(6)	275:14-24;276:1-5
Watson (supsidy of Teva)	John Hassler (30)(b)(6)	275:14-24;276:1-5

On February 15, 2013, Endo submitted a labeling supplement proposing additions to the label including "pre-and postmarketing data from in vitro and in vivo abuse potential studies to the DRUG ABUSE AND DEPENDENCE section of the Package Insert." ENDO-OR-CID-

01174358. On May 10, 2013, the FDA denied the application and highlighted the following concerns about the formulation:

no pharmacokinetic studies measuring serum concentrations following nasal administration or assessing the ability to insufflate have been conducted. Additionally, no human abuse liability studies examining abuse by the nasal route of administration have been conducted. The ease with which the product can be manipulated, and the ease with which oxymorphone can be extracted from the manipulated product, are not consistent with a formulation that would provide a reduction in oral, intranasal or intravenous abuse of Opana ER. *Id.* at *58-59.

The FDA also cited concerns with the post marketing data Endo submitted in support of the label change. The FDA found,

[t]he postmarketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse of Opana ER due to:

- the short period of time represented
- the overlap of prescriptions for both the original formulation of OPANA ER and reformulated OPANA ER during the first quarter of the reporting period
- the continued availability of original OPANA ER throughout the reporting period
- the possible misclassification of the original and reformulated products based on the similar appearance of the two products.

ENDO-OR-CID-01174359.

Mallinckrodt

Overall launch/brand/marketing plans

- a) MNK-T1-0000126200, MNK Power Point presentation re: marketing MNK-795 (extended release formulation of oxycodone and acetaminophen)
- b) MNK-T1_0000110204, Mallinckrodt Power Point presentation "Situation Analysis" on opioid prescription market and potential market for Xartemis XR and MNK 155
- c) MNK-T1-0000124210, MNK PowerPoint presentation re business results, marketing strategy, and market overview for EXALGO
- d) MNK-T1_0000535244, e-mail chain re marketing to physicians
- e) MNK-T1-0000130448, E-mail re marketing message for XARTEMIS XR

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- f) MNK-T1-0000132919, Internal instructions to sales teams re XARTEMIS sales; See also. MNK-T1_0000132938.
- g) MNK-T1-0000228064, PowerPoint presentation re marketing strategy for promoting MNK-795
- h) MNK-T1-0000136453, Leave-Behind for marketing XARTEMIS
- i) MNK-T1_0000110977, e-mail re distribution of Medsaway
- j) MNK-T1_0000102151
- k) MNK-T1_0000132471, e-mail ad copy for Xartemis
- l) MNK-T1_0000132411, digital leave behind
- m) MNK-T1_0000546808, sales rep compensation plan
- n) MNK-T1_0000468961, discusses global strategic marketing plan
- o) MNK-T1_0000222031, Advocacy and Pain Franchise presentation

Disease awareness/chronic pain as a condition

- a) MNK-T1_0000117179

Detailing – who’s targeted, frequency of visits, key issues from scripts and call notes

- a) MNK-T1_0000113374, power-point for sales reps
- b) MNK-T1_0000542035, e-mail re pharmacy and doctor profiling
- c) MNK-T1_0000541200, sales newsletter discussing meeting with doctors
- d) MNK-T1_0000136719, PowerPoint re market research on Xartemis XR
- e) MNK-T1_0000207584, proposed manuscript re targeting physicians
- f) MNK-T1_0000093660 through 93682
- g) MNK-T1_0000542039, Instructions and screenshots of pharmacy profiling system.
- h) MNK-T1_0000546493, Presentation about “high value physicians”
- i) MNK-T1_0000541200, sales newsletter
- j) MNK-T1_0000130216, e-mail re Xartemis Sales
- k) MNK-T1_0000545754, e-mail re Xartemis Sales
- l) MNK-T1_0000545281, e-mail re sales rep results
- m) MNK-T1_0000255243, presentation re targeting opioid prescribers

Copayment Cards/Vouchers/Rebates

- a) MNK-T1_0000541720
- b) MNK-T1_0000286297, chargeback reports for sales of Oxy 15 and 30
- c) MNK-T1_0000540013, PowerPoint re marketing expenses and relates for FY13
- d) MNK-T1_0000193448
- e) MNK-T1_0000215747, promotional material that explains PPI program
- f) MNK-T1_0000227707, Contract with AmerisourceBergen for rebates in 2010

- g) MNK-T1_0000506620, Rebate information for 2006-2007 for KeySource medical
- h) MNK-T1_0000508354, E-mail re Vault incentive program
- i) MNK-T1_0000508355, Data for sales relating to Vault incentive program
- j) MNK_T1_0000483901, Data on chargebacks and rebate programs for October FY11

Specific Misrepresentations

- a) MNK-T1_0000180846, email discussing marketing strategy for MNK 795, "the profile is less-liked by recreational drug abusers due to the controlled release, which makes it a potentially less abusable alternative to Percocet and Oxycontin"
- b) MNK-T1_0000111315 Email update from Melissa Falcone to the Brand Sales Team "SCORE," discussing the messaging around Xartemis XR and Exalgo
- c) MNK-T1_0000116055 E-mail discussing Pharmacy messaging
- d) MNK-T1_0000113702, presentation summaries for Xartemis XR ad campaign
- e) MNK-T1_0000125729, EXALGO Presentation
- f) MNK-T1_0000102151, guide for media inquiries
- g) MNK-T1_0000132471, e-mail ad copy for Xartemis
- h) "[T]he majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others. "Date: 2013. Source: Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse at 3, <https://www2.mallinckrodt.com/WorkArea/DownloadAsset.aspx?id=2147485834>

Promotion of the book Defeat Chronic Pain Now!

- a) "The bottom line: Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction. "Date: 2012. Book is still available online. Source: Mallinckrodt promoted a book through C.A.R.E.S. Alliance: Defeat Chronic Pain Now! p. 177 <http://www.defeatchronicpainnow.com/>
- b) "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain. "Defeat Chronic Pain Now! at p. 178.
- c) "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy." Date: 2012. Book is still available online. Source: Mallinckrodt promoted a book through C.A.R.E.S. Alliance: Defeat Chronic Pain Now! at p. 174

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- d) "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving." Date: 2012. Book is still available online at p. 176.
- e) "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction." FDate: 2012. Book is still available online. at p. 179.

Medsaway Initiative for Patient Safety Awareness

- a) MNK-T1_0000546362
- b) MNK-T1_0000546404

Government Affairs

- a) MNK-T1_0000214460, Government Affairs Presentation
- b) MNK-T1_0000239120, Advocacy and Government Affairs Tactical Plan by Kevin Webb

Coordination with other Defendants

- a) MNK-T1_0000227707, Presentation on collaboration between Endo and MNK to promote MNK-795
- b) ALLERGAN_MDL_01239440, Document showing coordination among manufacturers for REMS (Risk Evaluation and Mitigation Strategy)
- c) ALLERGAN_MDL_01237617, Joint Meeting of the Anesthetic and Life Support Drugs and Drug Safety and Risk Management Advisory Committee on drug safety and REMS for Extended-Release and Long-Acting Opioid Products
- d) ALLERGAN_MDL_01188848, speaker presentation for risk mitigating efforts
- e) ALLERGAN_MDL_01358391, presentation re joint meeting and weekly All Hands All, Opioid REMS Program Management
- f) ENDO-CHI-LIT_00238974, joint meeting presentation re risk management advisory committees

In addition, thousands of video messages with false or misleading statements were disseminated by Purdue and others. By way of example, see:

ENDO-CHI_LIT-00037637
ENDO-CHI_LIT-00058655
ENDO-CHI_LIT-00334741
JAN00023015
PMT000328743

PMT000328849
PMT000328906
PURCHI-000526551
PURCHI-000822872

Plaintiff specifically reserves the right to supplement, modify, and amend this response upon further investigation. Discovery into these topics is ongoing and will be the subject of fully-supported and detailed expert witness opinion(s).

Interrogatory No. 11:

Identify all individuals with knowledge concerning the subject matter of the Complaint in the above-captioned matter, including individuals who are likely to have discoverable information. For each, describe the subjects on which they have knowledge or information.

Response:

Plaintiff repeats and reasserts its prior objections and adopts its prior responses to this Interrogatory. Plaintiff objects to this Interrogatory as overly broad and unduly burdensome in that seeks “all individuals with knowledge concerning the subject matter of the Complaint in the above-captioned matter, including individuals who are likely to have discoverable information.” Read literally, this Interrogatory could include every employee and citizen of Summit County or the City of Akron, Ohio, every employee of the Manufacturer Defendants, and numerous third-parties around the country.

Plaintiff further objects in that this interrogatory asks for witness lists in advance of the completion of fact discovery that is underway, expert discovery that is upcoming and deadlines set pursuant to Case Management Order No. 1, paragraphs 3(e)(ii), 3(f), 3(h), and 3(i). Plaintiff objects based on undue burden to the extent this interrogatory seeks the disclosure and discovery of fact and expert witnesses prior to the express provisions of Case Management Order No. 1.

Plaintiff objects in that this interrogatory seeks to require Plaintiff to disclose witnesses contrary to the discovery procedures set forth in Case Management Order No. 1, paragraph 9(b). Plaintiff objects to the extent this interrogatory asks for persons already identified in Plaintiff's prior discovery responses.

Subject to and without waiving all objections, Plaintiff responds as follows: the table provided below identifies individuals who are likely to have discoverable information.

Name	Title	Jurisdiction
Honorable Joy Malek Oldfield	Judge, Court of Common Pleas; Member of Summit County Opiate Task Force and Turning Point Court Judge	Summit
Honorable Thomas Teodosio	Judge, Ninth District Court of Appeals; Member of Summit County Opiate Task Force, former Common Pleas Judge responsible for Turning Point Court	Summit
Dr. Lisa Kohler	Chief Medical Examiner, Summit County	Summit
Gary Guenther	Chief Investigator, Summit County Medical Examiner's Office	Summit
John Galonski	Civil Division, Summit County Prosecutor's Office	Summit
Brad Gessner	Criminal Division, Summit County's Prosecutor's Office	Summit
Laurie Fischer	Probation Supervisor, Court of Common Pleas, Second Division	Summit
Donna Skoda	Health Commissioner	Summit
Honorable Christine Croce	Judge, Court of Common Pleas, Turning Point Court Judge	Summit
Brian Nelson	Director of Finance and Budget	Summit
Steve Perch	Chief Toxicologist, Medical Examiner's Office	Summit
Sherri Bevan Walsh	Prosecutor	Summit
Steve Barry	Sheriff	Summit
Matt Paolino	Captain, Sheriff's Office	Summit
Ilene Shapiro	County Executive	Summit
Kim Patton	ADM	Summit
Dr. Gary L. Thrasher	Medical Director, ADM Detox Unit – Crisis Center, Oriana House, Inc.	Summit
Steve Fricker	Deputy Director of Finance	Akron
Judge Jon Oldham	Presiding Judge, Recovery / Drug Court	Akron
Chief Kenneth Ball	Police Chief, formerly Deputy Chief, Investigative Subdivision	Akron
Officer Michael Schmidt	Officer, Narcotics Unit, opioid heroin overdose death investigator	Akron
Cpt. Michael Shearer	Captain, Narcotics, SNUDS, Vice Subdivision	Akron

Name	Title	Jurisdiction
Chief Clarence Tucker	Chief of Fire Division	Akron
Deputy Chief Charles Twigg	Deputy Chief of Fire Division	Akron
District Chief Joseph Natko	District Chief / EMS Bureau Manager	Akron
Gert Wilms	Chief Prosecutor	Akron
Tony Ingram	Chief Probation Officer	Akron
Donald L. Plusquillic	Mayor (1987 – 2015)	Akron
Garry Moneypenny	Mayor (5/31/2015 – 6/10/2015)	Akron
Jeff Fusco	Mayor (6/11/2015 – 1/1/2016)	Akron
Dan Horrigan	Mayor (1/1/2016 – present)	Akron
Craig Morgan	Deputy Prosecutor	Akron
Sandra Kurt	County of Summit Clerk of Courts	Summit
Dr. Lisa Kohler	Chief Medical Examiner, Summit County	Summit
John Galonski	Civil Division, Summit County Prosecutor's Office	Summit
Brad Gessner	Criminal Division, Summit County's Prosecutor's Office	Summit
Laurie Fischer	Probation Supervisor, Court of Common Pleas, Second Division	Summit
Rich Marountas	Chief Epidemiologist	Summit
Leanne Beavers	Director of Clinical Health	Summit
Donna Skoda	Health Commissioner	Summit
Jerry Craig	Executive Director, ADM	Summit
Doug Smith	Doctor, ADM Chief Clinical Officer, ADM	Summit
Mary Alice Sonnhalter	Retired, ADM	Summit
Aimee Wade	ADM Assoc. Dir. Of Clinical Services, ADM	Summit
Brian Nelson	Director of Finance and Budget	Summit
Lisa DiSabato-Moore	Special Projects Administrator, Juvenile Court	Summit
Curtis Howard	Chief Probation Officer, Juvenile Court	Summit
Getta Kutuchief	Education and Community Outreach Coordinator, Juvenile Court	Summit
Becky Ryba	FRRC Coordinator (Family Reunification through Recovery Court), Juvenile Court	Summit
Kathryn VanHorn	Crossroads Supervisor, Juvenile Court	Summit
Denice DiNapoli	Senior Administrator, Medical Examiner's Office	Summit/Akron
Sherri Bevan Walsh	Prosecutor	Summit
Melanie Hart	Administrative Assistant to Sherri Bevan Walsh, Prosecutor	Summit
Kelly Pongracz	Records Manager, Sheriff's Office	Summit
Bill Holland	Public Information Officer, Sheriff's Office	Summit
Pat Hunt	Staff, Sheriff's Office	Summit
Kim Patton	ADM	Summit

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Name	Title	Jurisdiction
Cpt. Brian Harding	Captain, Technical Services Bureau	Akron
Steve Fricker	Deputy Director of Finance	Akron
Judge Jon Oldham	Presiding Judge, Recovery / Drug Court	Akron
Montrella Jackson	Administrator	
Charles Brown	Deputy Mayor for Public Safety, formerly Assistant to the Mayor	Akron
Craig Gilbride	Formerly Deputy Mayor for Public Safety, Chief of Police (retired)	Akron
Robert Ross (retired)	Formerly Deputy Mayor for Public Safety, Fire Chief (retired)	Akron
Chief Kenneth Ball	Police Chief, formerly Deputy Chief, Investigative Subdivision	Akron
Patrick Leonard	Detective, Police Department	Akron
Deputy Chief Michael Caprez	Deputy Chief, Uniform Subdivision, formerly Deputy Chief, Communications Subdivision	Akron
Deputy Chief Jesse Leaser	Deputy Chief, Investigative Subdivision, formerly Captain, Technical Services Bureau	Akron
Sgt. Eric Wood	Sergeant, Chief's Office	Akron
Deputy Chief Paul Calvaruso (retired)	Formerly Deputy Chief, Patrol Subdivision (retired)	Akron
Cpt. Sylvia Trundle (retired)	Formerly Captain, Investigative Subdivision (retired)	Akron
Cpt. Terry Pasko	Captain, Patrol Subdivision, formerly lieutenant, street narcotics unit (SNUDS)	Akron
Officer Michael Schmidt	Officer, Narcotics Unit, opioid heroin overdose death investigator	Akron
Officer Tim Harvey	Officer, Narcotics Unit, opioid heroin overdose death investigator	Akron
Officer Patrick Didyk	Officer, Street Narcotics (SNUDS) Unit, opioid heroin overdose death investigator	Akron
Officer Timothy Wypasek	Officer, Street Narcotics (SNUDS) Unit, opioid heroin overdose death investigator	Akron
Erika Wiles	Crime Analyst II, Planning and Research Office	Akron
Cpt. Michael Shearer	Captain, Narcotics, SNUDS, Vice Subdivision	Akron
Lt. David Garro	Lieutenant, Narcotics Unit	Akron
Cpt. Chip Westfall (retired)	Formerly Lieutenant, Narcotics Unit (retired)	Akron
Lt. Rick Edwards	Police Information Officer	Akron
Cpt. Melissa Schnee	Captain, Services Subdivision	Akron
Cpt. Daniel Zampelli (retired)	Formerly Captain, Services Subdivision (retired)	Akron
Chief Clarence Tucker	Chief of Fire Division	Akron
Chief Ed Hildebrand (retired)	Formerly Chief of Fire Division (retired)	Akron

Name	Title	Jurisdiction
Deputy Chief Charles Twigg	Deputy Chief of Fire Division	Akron
District Chief Joseph Natko	District Chief / EMS Bureau Manager	Akron
District Chief Rich Vober	Deputy Chief	Akron
Cpt. Leon Henderson	Captain, Safety Communications	Akron
Cpt. Chris Karakis	Captain, EMS Bureau Manager	Akron
District Chief Jim Willoughby	District Chief, formerly Captain, EMS Bureau Manager	Akron
Deputy Chief Dale Evans (retired)	Formerly Deputy Chief, EMS Bureau Manager (retired)	Akron
Lt. Joseph Shumaker	Lieutenant, Fire / EMS	Akron
Albert Minnich (retired)	Formerly fire medic (retired)	Akron
Les Gaiser (retired)	Formerly Captain, Fire / EMS (retired)	Akron
Guy Randall	Fire / EMS medic, training	Akron
Lt. Sierjie Lash	Public Information Officer	Akron
Terry Albanese (retired)	Assistant to the Mayor for Education, Health, and Families	Akron
Gert Wilms	Chief Prosecutor	Akron
Tony Ingram	Chief Probation Officer	Akron
Jeff Sturmi	Deputy Chief Probation Officer	Akron
Craig Morgan	Deputy Prosecutor	Akron
Gary L. Thrasher	Doctor, Oriana House, Inc.	Akron

Name	Title	General description
Dr. William Reed	Doctor	Visited by drug reps: Nucynta, Purdue, Actiq, Opana, Kadian
Dr. William Lonsdorf	Doctor	Visited by Purdue, Opana, Nucynta,
Dr. Kendrick Bashor	Doctor	Visited by drug reps: Purdue
Dr. Michael Louwers	Doctor	Visited by drug reps: Purdue, Xtampza, Nucynta, Actiq/Fentora
Dr. Syed Ali	Doctor	Visited by drug reps: Purdue, Xtampza, Nucynta-Janssen/Depomed, Teva, Subsys, Endo, Cephalon, Xalgo, Kadian, Insys
Dr. Clayton Seiple	Doctor	Visited by drug reps: Purdue. Was a speaker for Endo, Depomed (Nucynta)

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Name	Title	General description
Bernie Rochford	Executive Vice President of Administrative Services and Business Relations, Oriana House	Treatment center for those suffering from OUD, knowledgeable on trends, prevalence and impact of opioids
Galen Sievert	Clinical Supervisor, Mature Services	Treatment center for those suffering from OUD, knowledgeable on trends, prevalence and impact of opioids
Laura Kidd	Behavioral Health Clinical Coordinator, AxxessPointe Community Health Center at Arlington	Treatment center for those suffering from OUD, knowledgeable on trends, prevalence and impact of opioids
James Orlando	President of Summit Psychological Associates	Treatment center for those suffering from OUD, knowledgeable on trends, prevalence and impact of opioids
Brittney Becker	Doctor, Community Health Center	Treatment center for those suffering from OUD, knowledgeable on trends, prevalence and impact of opioids
Michael M. Huges	President, Summa Health System, Barberton Campus	Illnesses related to opioid use
Joseph P. Myers	Doctor, Vice President of Medical Affairs, Summa Barberton and Summa Wadsworth-Rittman Hospitals	Illnesses related to opioid use
Roslyn Greene	Family member	Personal loss
Charlene Maxen	Pediatric oncologist nurse, Akron Children's Hospital	Personal loss
Travis and Shelly Bornstein	Family member	Personal loss
Dr. Tony Lababidi	Doctor	Visited by drug reps: Purdue, Endo, Janssen
Dr. Laura Novak	Doctor	Visited by drug reps: Purdue
Dr. Adolph Harper	Doctor	Visited by drug reps
Reba McCray	Family member	Personal loss
Josh Vandergriff	Family member	Personal loss

Name	Title	General description
Dr. Ann DiFrangia	Specializes in treatment of substance use disorders	Addiction
Aimee Wade	Family member	Personal loss
Dr. Nicole Labor	Family member	Personal loss & addiction
Greg McNeil	Family member	Personal loss
Romona Harrison	Former receptionist for Dr. Adolph Harper from 2010 through January 2012	Pill mills
Roxann Montgomery	Former sales representative with Purdue Pharma from 2008 to 2012	Sales
Dana Spora	Former sales consultant with Endo Pharmaceuticals from July 2006 to June 2013	Sales
Julie Yellin	Former sales consultant with Endo Pharmaceuticals from March 2006 to June 2013	Sales
Lisa McDougall	Former sales representative for Endo Pharmaceuticals from 2004 to 2010	Sales
Carol Panara	Former sales representative for Purdue Pharma from 2008 to January 2013	Sales
Kirk Klaazesz	Former sales supervisor for ParMed Pharmaceuticals from 2011 to 2014	Sales
Gregory Bowman	Former sales specialist for Covidien and Mallinckrodt from 2010 to 2014	Sales

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Name	Title	General description
Richard Bradley Pate	Former pharmacy manager for Walgreens from 2009 to 2014	Diversion
David Schatz	Former sales representative for Purdue Pharma from 2000 to 2001	Sales
William Harris	Former sales representative for Cephalon and Teva from November 2005 to 2012	Sales
Marcia Smith-Anderson	Former pharmacy manager for Walgreens from 2000 to 2012	Diversion
Larry Hunley	Former distribution center manager for McKesson Corporation from 2004 to September 2011	Diversion
Ashley Bhalla	Former sales representative for Purdue Pharma from 2012 to 2018	Sales
Daniel Smith	Former contract sales representative for Mallinckrodt from 2014 to 2015	Sales
Betty Singleton	Former pharmacist with Rite Aid Corporation from January 2010 to October 2017	Industry conduct
Karen Chapman	Former inventory manager for McKesson Corporation from October 1983 to October 2014	Industry conduct
Gertrude Kass	Former sales representative for Purdue Pharma from January 2013 to May 2015	Sales
Russell Portenoy	Executive Director of the MJHS Institute for Innovation in Palliative	Industry conduct

Name	Title	General description
	Care and Chief Medical Officer of MJHS Hospice and Palliative Care	
Alston Hammons	Former pharmacist with CVS from 2006 to 2013	Industry conduct
Martha Davis	Former district manager for Purdue Pharma from 1991 to 2003	Industry conduct
Julie Fuller	Former account manager with AmerisourceBergen Corporation from December 2003 to January 2007	Industry conduct
James Shriner	Former regional sales director for Mallinckrodt from 2002 to 2008	Sales

Plaintiff also identifies all witnesses deposed in this litigation as listed on Exhibit 11A. This list is not intended to be an exhaustive description of all persons with knowledge or all knowledge held by a particular individual or type of individual regarding issues involved in the case. By indicating the general subject matter(s) of discoverable information these individuals may possess, Plaintiff is in no way limiting its right to call other individuals (or entities) to testify concerning other subjects.

Plaintiff specifically reserves the right to rely on these and any other individuals for testimony in any trial or in a summary judgement motion in this action, and is not limited to the individuals listed herein. Plaintiff reserves its right to amend or supplement this response based on facts learned in expert discovery, third party discovery, or otherwise discoverable in this litigation prior to trial.

Interrogatory No. 12:

Identify all medical or scientific research, data, information, literature or other documents or communications that Plaintiff believes or maintains supports, underlies, and/or forms the basis for Plaintiff's claims in this litigation.

Response:

Plaintiff repeats and reasserts its prior objections and adopts its prior responses to this Interrogatory. Plaintiff incorporates its prior objections and objects to this Interrogatory as vague, ambiguous, overly broad and unduly burdensome to the extent it requests "all" medical or scientific research, data, information, literature or other documents or communications that Plaintiff believes or maintains supports, underlies, and/or forms the basis for Plaintiff's claims in this litigation. There is a vast amount of peer-reviewed scientific literature, testimony before public entities, information in the public domain, testimony and evidence in this case equally available to Defendants, which may provide the answer, at least in large part, to Defendants' Interrogatory. Plaintiff further responds that this Interrogatory is contention discovery more appropriately answered once discovery is completed and calls for information likely to be the subject of expert reports. *See* FRCP 33(a)(2). Subject to and without waiving all objections, Plaintiff responds as follows:

Plaintiff refers Defendants to Plaintiff's Second Amended Corrected Complaint, which specifically identified medical or scientific research, data, information, literature or other documents or communications, and to the documents listed on Exhibit 12A with the following caveat: the identification of medical or scientific research, data, information, literature or other documents or communications listed in Exhibit 12A is not to be construed as an admission by Plaintiffs or its experts they necessarily agree with everything contained in those materials.

Plaintiff reserves the right to supplement or amend this response as expert discovery commences. In addition this topic may be the subject of fully-supported and detailed expert witness opinion(s) that will be disclosed in accordance with expert discovery.

Interrogatory No. 13:

Identify and describe all disciplinary matters, investigations, complaints, arrests, indictments, prosecutions, or attempts by each Plaintiff, or anyone acting on Plaintiff's behalf, to identify drug abusers, health care providers, or others involved in unlawful activity or prescribing practices related to opioids.

Response:

Plaintiff repeats and reasserts its prior objections and adopts its prior responses to this Interrogatory. Plaintiff objects to this Interrogatory to the extent that it calls for disclosure of Privileged and Confidential Information. Plaintiff objects to this Interrogatory as overly broad and unduly burdensome and seeking information beyond Plaintiff's possession, custody, and control. Further objecting, the Interrogatory contains a reference to several undefined terms and phrases, namely, "wrongfully," "geographical boundaries," and "dispensed."

Subject to and without waiving all objections, Plaintiff's investigation of the wrongful conduct of Defendants including the identification of wrongful diversion of prescription opioids and other wrongful conduct within the County and will be the subject of fully-supported and detailed expert witness opinion(s) that will be disclosed in accordance with the scheduling orders and the Federal Rules of Civil Procedure. Plaintiff incorporates by reference its responses to Distributor Defendants' Interrogatory Nos. 2, 3, and 8; Manufacturer Defendants' Interrogatory No. 20, and National Retail Pharmacy Defendants' Interrogatory Nos. 2, 3 & 4, 15 and 16.

Subject to and without waiving all objections, Plaintiff answers the following parties “wrongfully” manufactured, sold or distributed opioids withing Plaintiff’s geographical boudnaries: Purdue Pharma, L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.; Janssen Pharmaceuticals, Inc. f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc. f/k/a/ Janssen Pharmaceutical, Inc.; Johnson & Johnson; Noramco, Inc.; Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Allergan PLC f/k/a Actavis PLC; Allergan Finance LLC, f/k/a/ Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc; Insys Therapeutics, Inc., Mallinckrodt PLC; Mallinckrodt LLC; AmerisourceBergen Drug Corporation, Anda, Inc.; Cardinal Health, Inc., Discount Drug Mart, Inc.; HBC Service Company; McKesson Corporation, Henry Schein Entities; CVS Health Corporation, Miami-Luken, Inc.; Prescription Supply, Inc.; Walgreens Boots Alliance, Inc. a/k/a Walgreen Co.; and Wal-Mart Inc., f/k/a Wal-Mart Stores, Inc..

Plaintiff further responds that local prescriber- and patient-level data is in the possession of the data mining companies frequently used by Defendants to monitor such information. These companies include, but are not limited to, IMS Health, QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and PRA Health Science. Pursuant to comments from the U.S. Department of Justice Drug Enforcement Administration (“DEA”), Defendants also compiled “know your customer” questionnaires and files that contain such data and information.

Plaintiff further answers as follows: Summit County investigations into diversion of opioids include, but are not limited to:

Bates	Date	Summary
SUMMIT_000038070	7/22/2011	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of "Initiative Activities," indicates one (1) pharmaceutical case involving a pharmacy
SUMMIT_000072338	4/28/2014	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of "Initiative Activities," indicates one (1) pharmaceutical case involving a doctor and one (1) pharmaceutical case involving a pharmacy
SUMMIT_000074754	3/13/2017	2016 Ohio Multi-Jurisdictional Task Force Report-stats on pharmaceutical/pharmacy and individual pharmacy employee investigations
SUMMIT_000076767	2/18/2010	Media Release by Sheriff Drew Alexander (Summit County) re: Pharmacy Burglars (Joshua Dowdell, James Devaughn, Thomas Farrell, Kyle Porkorney, and Joshua Weigand) Arrested; pill taken include Oxycontin, Hydrocodone, Vicodin, and various other pills
SUMMIT_000076823	7/20/2012	Summit County Drug Unit Confidential Investigative Report re: Fictitious Prescription Investigation; Suspects were calling in prescriptions for pain killers under Dr. Chen's DEA number; phoned in by Susan Glover (later determined to be Jamie Boasko aka Jamie Hammonds) for Nicke/Nicolis Cramer. William J. Stoddard also involved.
SUMMIT_000077487	4/17/2018	Draft Affidavit by TFO Lori A. Baker-Stella re: investigation of persons engaged in large-scale drug trafficking which included Percocet and Fentanyl/Oxycodone Hydrochloride. Notes controlled drug purchases from Gerald "Bowman" or "Bowerman" and Courtney Lee Williams who have been identified as "mid-level distributors of Percocets and Marijuana in the Akron-Cleveland, Ohio area"
SUMMIT_001000530	7/18/2014	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of "Initiative Activities," indicates one (1) pharmaceutical case

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Bates	Date	Summary
		involving a doctor and one (1) pharmaceutical case involving a pharmacy
SUMMIT_001002135	11/20/2008	11/2008 DB Intel Meeting @ SUMMIT_001002136 report of burglary at Ritzman Pharmacy; large amount of Oxycontin stolen
SUMMIT_001006223	10/7/2016	January – June: 2016 Ohio Multi-Jurisdictional Task Force Report--gives stats on pharmaceutical/pharmacy/and individual pharmacy employee investigations
SUMMIT_001006365	12/2/2016	Drug Interdiction, Disruption and Reduction Plan for the Ohio Department of Public Safety "... OCJS-funded task forces participated in pharmaceutical diversion investigations in 2014. Task forces initiated 1,261 pharmaceutical diversion investigations and indicted 716 individuals, 90 of whom were health care professionals." Examines Ohio overall SUMMIT_001006374
SUMMIT_001130107	10/2/2009	Media release from Sheriff Drew Alexander, Summit County, re: Sheriff's Patrol responding to Rite-Aid in response to information about female (Andrea Strickland) attempting to illegally obtain Vicodin.
SUMMIT_001129537	4/30/2015	Email from Daniel Lance to many individuals forwarding an email from Barberton Detective Robert Russell re: a robbery of Rite Aid Pharmacy in which suspect took "a few bottles of Hydrocodone."
SUMMIT_001132080	3/17/2015	Akron/Summit Case Chart including Total number of Pharmaceutical Cases involving a doctor and cases involving a pharmacy in 2014; also broken down by Akron, and Summit individually.
AKRON_000321799	8/10/2017	Daily report for 8/10/2017 for Akron Police Department; includes report of CVS pharmacy being robbed of narcotics and pain medications
AKRON_000322914	9/25/2017	Daily report for 9/25/2017 for Akron Police Department; includes report of CVS pharmacy being robbed of various medications; does not mention opioids but does contain a report number that could possibly be cross-referenced

Bates	Date	Summary
AKRON_000325028	7/18/2017	Daily report for 7/18/2017 for Akron Police Department; includes report of CVS pharmacy being robbed of miscellaneous pain medications
AKRON_000330904	5/10/2012	Report on Walgreen's being robbed of Percocet and Ambian
AKRON_000334652	2/17/2015	Report of CVS Pharmacy robbed for Oxymorphone at gunpoint
AKRON_000332821	3/24/2014	Benjamin D. Grim found with Percocet
AKRON_000333698	4/7/2014	Daily Report of Major Incidents including individual, Reginald D. Provo, charged with deception to obtain a dangerous drug (counterfeit prescription of Promethazine with Codeine)
AKRON_000334661	2/23/2015	Report of individual, Andrew P. Norris, attempting to obtain Oxycodone by using an altered prescription
AKRON_000335090	3/24/2014	Report of individual, Benjamin D. Grim, found with Percocet
SUMMIT_001233768 Duplicate of SUMMIT_000077487 Above.	4/18/2018	Draft Affidavit by Lori A. Baker-Stella re: search warrant related to group of individuals distributing Percocet; Notes controlled drug purchases from Gerald "Bowman" or "Bowerman" and Courtney Lee Williams who have been identified as "mid-level distributors of Percocets and Marijuana in the Akron-Cleveland, Ohio area"
AKRON_000335673	2/23/2015	Report of individual, Andrew P. Norris, attempting to obtain Oxycodone by presenting an altered prescription to a pharmacy.
SUMMIT_001233883	11/20/2008	Report of pharmacy being robbed of a large amount of Oxycontin
AKRON_000335652	2/16/2015	Report of CVS Pharmacy attempted robbery of Oxymorphone
AKRON_000337173, AKRON_000337174	3/1/2016	Email and media release from Summit County's prosecutor's office reporting the sentencing of Alexander Linton for robbing several pharmacies of Oxycodone/Oxymorphone at gunpoint
AKRON_000338005	9/23/2015	Report of CVS Pharmacy attempted robbery of Oxymorphone by Alexander Linton

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Bates	Date	Summary
AKRON_000338159	5/9/2016	Akron Police Incident Report re: Christopher Richard, pharmacy technician at AGMC; alleged to have stolen a syringe of Fentanyl for personal use
SUMMIT_001444150	6/8/216	Email from Pat Hunt to Lori Baker-Stella responding to Baker-Stella's email relaying, in part, that she has several complaints from the Ohio Pharmacy Board that she is currently working
AKRON_000367833	10/5/2016	Email between Patrick Leonard and Colleen Sims (prosecutor's office) re: 45 doctors in Ohio prescribing pain killers without running required checks and trying to find out if any of these doctors are in Summit County
AKRON_000368167	7/1/2010	Report of Investigation: Thelma E. Arnold arrested for filling a prescription for Oxycodone (Percocet) for a dead person
AKRON_000368449	3/22/2013	Fax sheet from Agent Thomas Miksch to Pharmacist re: Hotline Information about a recently forged prescription passed in Summit County from Doctor's Pain Clinic in Youngstown, OH.
AKRON_000368453	1/18/2013	Fax sheet from Agent Thomas Miksch to Pharmacist re: Hotline Information about prescriptions from a doctor or doctors in the State of Georgia being bought in Ohio to be filled
SUMMIT_001444634	9/16/2013	Email from Pat Hunt to Lori Baker-Stella responding to Baker-Stella's email relaying some data entry she is doing "for our Pharmacy case."
AKRON_000366415, AKRON_000366435	9/23/2017	Emails from Walgreens to Summa Barberton and from Gregory Smith to Walgreens with Patrick Leonard copied re: Summa Barberton ERs OARRS practices. This email was in response to issues Walgreens noted with Summa Barberton ERs prescriptions
AKRON_000368006	10/28/2009	Email from Tom Miksch (agent with the Board of Pharmacy) to Patrick Leonard re: Walgreen B&E; 8000 to 9000 Percocet and Oxycontin stolen
AKRON_000368458, AKRON_000368459	1/14/2013	Email from Tom Miksch to Patrick Leonard and others re: Pearl Lantz interview with attached Ohio State Board of Pharmacy Report of Investigation on Adolph Harper, MD for his pain management practice

Bates	Date	Summary
AKRON_000368462, AKRON_000368463	12/23/2012	Email from Tom Miksch to Patrick Leonard and others re: Interview of Harper patient Sarah Weiss with attached Ohio State Board of Pharmacy Report of Investigation on Adolph Harper, MD for his pain management practice
AKRON_000368471	8/5/2013	Email between Terry Pasko and Patrick Leonard re: problem with people reporting prescriptions lost or stolen and physicians having to write new prescriptions; discussion on developing a file to see if the same individuals or physicians are involved
AKRON_000368700	1/27/2014	Email thread including email from Tom Miksch to Patrick Leonard re: completed case of pharm tech stealing drugs from Walgreens
AKRON_000368707, AKRON_001100769	12/10/2013	Emails from Patrick Leonard to Tom Miksch re: open case on a nurse diverting narcotics at Wyant Woods
AKRON_000368712	10/30/2013	Email from Patrick Leonard to Tom Miksch about investigating fake "Prometh-Codeine" scripts that have flooded the area near Green, Ohio
AKRON_000369026	12/11/2012	Email from Tom Miksch to Cathy Hanselman and others including Patrick Leonard re: Summit County Coroner Reports; also attaches a death report of a Harper patient who died of a heroin/alcohol combo
AKRON_000369048	1/21/2013	Email from Tom Miksch to Patrick Leonard and others re: Kelly Pamer Autopsy Report from Medina County; also attaches a death report of a Harper patient who died of a alpraxolam/oxycodone combo
AKRON_000369079	12/9/2013	Fax sheet from Agent Thomas Miksch to Pharmacist re: Hotline Information about illegal prescriptions for controlled substances (hydrocodone products) being phoned in to pharmacies in Summit County by a person posing as Andrew Staub, CNP
AKRON_000369106, SUMMIT_001520506	1/22/2014	Email from Hugh Schuckman to Patrick Leonard re: Jessica Bittinger, patient with OARRS Percocet issue; Akron Police Report of Investigation regarding same
AKRON_000369105	1/10/2014	Medina County Drug Task Force Pharmacy Alert – Statewide: Compromised DEA Numbers to obtain

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Bates	Date	Summary
		Codeine w/Promethazine. Physician office located in Wadsworth, Akron, and Canton
AKRON_000369111	1/23/2014	Fax sheet from Agent Thomas Miksch to Pharmacist re: Hotline Information about Promethazine w/Codeine Rx's being called in along with drugs like Prednisone using a prescriber name of Timothy Billups
AKRON_000369180, AKRON_000369181	3/7/2014	Email and attached Fax sheet from Agent Thomas Miksch to Pharmacist re: Hotline Information about forged prescriptions being passed in Summit County on blanks from Summa Western Reserve Hospital using prescriber name Kevin D. Cox for Sandra Lester; scripts are for Ambian and Roxicodone
AKRON_000369200	3/28/2014	Fax sheet from Agent Thomas Miksch to Pharmacist re: Hotline Information about illegal prescriptions phoned in for Phenergan with Codeine using Dr. Chimezie Amanambu, MD's name
AKRON_000369430, AKRON_000369431	11/28/2014	Email and attached Fax sheet from Agent Thomas Miksch to Pharmacist re: Hotline Information about an unarmed pharmacy robbery in Stow; suspect asked specifically for oxymorphone and oxycodone
AKRON_000369432, AKRON_000369433	12/4/2014	Email and attached Fax sheet from Agent Thomas Miksch to Pharmacist re: Hotline Information about forged prescriptions presented at Summit County pharmacies from Dr. Cynthia Weinstein for a patient for Percocet
AKRON_000369539, AKRON_000369555	3/27/2015	Emails from Hugh Schuckman to Patrick Leonard re: person lying to pharmacy about 90 hydrocodone script being stolen
AKRON_000369671, AKRON_000369672	8/6/2015	Email from Helene Hall (Ritzman Pharmacy) to Patrick Leonard re: an individual selling percocets and having prescriptions filled at the pharmacy
AKRON_000369677	9/10/2015	Email from Michael Caprez to Patrick Leonard re: Lisa Aurilio trying to report a nurse that works at ACH who admitted taking Dilaudid and other scheduled narcotics from the hospital; says Leonard has not returned her calls
AKRON_000369680	7/31/2015	Heavily redacted U.S. DOJ DEA report re: RX Fraud/Forgery at Walgreen's.

Bates	Date	Summary
AKRON_000370688	10/1/2015 – 12/31/2015	National Diversion Survey Questionnaire; lists number of cases involving particular drugs including opioid during the reporting period
AKRON_000369897, AKRON_000369898	1/27/2016	Email from Cassandra Grizer to Patrick Leonard re: VCA Green Animal Hospital Tramadol Case; Notes on incident involving a suspect Tramadol prescription
AKRON_000370155, AKRON_000370702	4/13/2016	Email from Patrick Leonard to Yamilka Stivers (RADARS Drug Diversion Project Manager) re: various opioid cases including liquid fentanyl being stolen from area hospitals; in one case an RN and the other by a pharmacy technicians (both for personal use)
SUMMIT_001461044	8/10/2005	2005 Ohio Office of Criminal Justice Services Byrne Memorial Grant Program; Area A: Law Enforcement Task Forces Semi-Annual Performance Report for the Summit County Drug Unit; stats for health professional involved in pharmaceutical diversion and dosages of drugs seized which include opioids
SUMMIT_001461060, SUMMIT_001461068	7/19/2006	2006 Ohio Office of Criminal Justice Services Byrne Memorial Grant Program; Area A: Law Enforcement Task Forces Semi-Annual Performance Report for the Summit County Drug Unit; stats for health professional involved in pharmaceutical diversion and dosages of drugs seized which include opioids
SUMMIT_001520521	5/31/2012	Akron Police Department Report of Investigation; arrest for attempting to obtain buprenorphine by illegal processing of a drug document
SUMMIT_001520532	6/21/2012	Akron Police Department Report of Investigation; arrest for attempting to obtain Oxycodone, Hydrocodone, and Alprazolam by illegal processing of a drug document
SUMMIT_001520537	11/9/2012	Akron Police Department Report of Investigation; arrest for trafficking in Percocet
SUMMIT_001520543	4/18/2012	Akron Police Department Report of Investigation; arrest for attempting to obtain Vicodin by deception

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Bates	Date	Summary
SUMMIT_001520558	2/3/2012	Akron Police Department Report of Investigation; arrest for attempting to obtain Oxycodone by deception
SUMMIT_001520564	1/31/2014	Akron Police Department Report of Investigation; arrest attempting to obtain Vicodin by deception and illegal processing of a drug document
SUMMIT_001520569	3/19/2012	Akron Police Department Report of Investigation; arrest attempting to obtain Oxycodone by deception
SUMMIT_001520581	2/3/2012	Akron Police Department Report of Investigation; arrest for attempting to obtain Oxycodone by deception
SUMMIT_001520586	1/11/2012	Police Department Report of Investigation; arrest for attempting to obtain Vicodin by deception and illegal processing of a drug document
SUMMIT_001520592	11/6/2013	Police Department Report of Investigation; arrest for attempting to obtain Promethazine w/Codeine by deception and illegal processing of a drug document
SUMMIT_001520597	6/25/2014	Police Department Report of Investigation; arrest for attempting to obtain Promethazine w/Codeine by deception and illegal processing of a drug document
SUMMIT_001520604	2/11/2014	Police Department Report of Investigation; arrest for attempting to obtain Oxycodone by deception and illegal processing of a drug document
SUMMIT_001520610	9/11/2012	Police Department Report of Investigation; arrests for trafficking narcotic, obtaining narcotics by deception and illegal processing of a drug documents. List of drugs obtained and presumably trafficked include prescription opioids.
SUMMIT_001520612	1/6/2012	Akron Police Department Report of Investigation; arrest for attempting to obtain Oxycodone by deception
AKRON_001127725	8/24/2016	Akron police department report/Zone Report on individual robbed of Oxycontin after leaving the pharmacy
AKRON_001128232	1/23/2017	Akron Police Department report/Zone Report on person who was found with a white substance that tested positive for Oxycodone

Bates	Date	Summary
AKRON_001128736	8/21/2017	Akron Police Department report/Zone Report; suspect alleged to have stolen 30 Percocet pills among other items from a private home
AKRON_001129036	8/10/2017	Akron Police Department report/Zone Report, person ODeD and admitted using three doses of Percocet along with heroin
AKRON_001130314	10/21/2016	Akron Police Department report/Zone Report, person found with a Hydrocodone pill in an empty cigarette pack that he said he got from his cousin
AKRON_001131558	9/25/2017	Akron Police Department report/Zone Report, persons found in vehicle with crushed up Suboxone and multiple syringes.
AKRON_001131778	9/5/2017	Akron Police Department report/Zone Report, Rite Aid pharmacy robbed of Oxycodone, percocet, and codeine
AKRON_001137270	7/1/2016	Akron Police Department report/Zone Report, unknown suspect, possibly drunk, threatened to "shoot up" CVS and asked for Percocets.
AKRON_001138256	8/9/2012	Northeast Ohio Regional Fusion Center Crime/Intel Bulletin; FBI Cleveland Division cites pattern of Walgreen pharmacy robberies across several states, including in Ohio, in which Oxycontin, Percocet, and other controlled substances are stolen
AKRON_001138590	12/30/2013	Daily Report of Major Incident includes report of Modesty S. Davis (Akron) "charged with deception to obtain a controlled substance and illegal processing of a drug document. Davis altered a prescription for a controlled narcotic and presented the prescription to an area pharmacy."
AKRON_001138792	4/7/2014	Daily Report of Major Incident includes report of person charged with attempting to refill a counterfeit prescription of Promethazine with Codeine.
AKRON_001138889	6/11/2014	Daily Report of Major Incident includes report of person charged with possession of Percocet when found with a blue pill crushed up on his lap.
AKRON_001139513	2/16/2015	Daily Report of Major Incident includes report of aggravated robbery in which suspect demanded Oxymorphone

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Bates	Date	Summary
AKRON_001139534	2/23/2015	Daily Report of Major Incident includes report of person charged with Deception to obtain and Illegal Processing of Drug Documents after he presented an altered prescription for Oxycodone to a pharmacy
AKRON_001139901	9/23/2015	Daily Report of Major Incident includes report of person who was charged with aggravated robbery of a CVS pharmacy after approaching the pharmacist with a handgun and demanding Oxymorphone.
AKRON_001140104	2/9/2016	Akron Police Department, City-wide Crimes Zone includes report of person who was charged with Deception to obtain a dangerous drug for stealing 112 dosage units of Oxycodone
SUMMIT_001520888	1/2013 – 3/2013	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of “Drug Report,” indicates multiple cases in which prescription opioids were seized
SUMMIT_001520917	2/27/2013	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of “Drug Report,” indicates multiple cases in which prescription opioids were seized
SUMMIT_001520945	7/27/2012	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of “Drug Report,” indicates multiple cases in which prescription opioids were seized
SUMMIT_001520946	10/30/2012	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of “Drug Report,” indicates multiple cases in which prescription opioids were seized
SUMMIT_001520947	1/16/2013	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of “Drug Report,” indicates multiple cases in which prescription opioids were seized
SUMMIT_001521058	4/15/2013	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of “Drug Report,” indicates multiple cases in which prescription opioids were seized
SUMMIT_001521059	4/5/2013	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of “Drug Report,” indicates multiple cases in which prescription opioids were seized

Bates	Date	Summary
SUMMIT_001521252	7/27/2012	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of "Drug Report," indicates multiple cases in which prescription opioids were seized
AKRON_001148928	11/6/2017	Akron Police Department City-wide Reports for the weekend; all zones report; includes report on person who was found with methamphetamine and four Hydrocodone pills; another report for burglary of a private residence including stolen Vicodin and Percocet; another report person who had a plastic baggie with 3 20 mg Oxycodone; another report of persons found with Oxycodone
AKRON_001150411	4/10/2017	Akron Police Department All Zones Reports; includes report of person who robbed her friend of 10 Percocet
AKRON_001151693	8/2/2011	Request for Service/Information Report: photo of suspect who stole 300 doses of Percocet from an Akron Walgreens.
AKRON_001153252	7/1/2014	Akron Police Department Zone Reports; includes report of medical office manager for Dr. Sheela Rao stating someone stole blank prescription forms and the office was notified by Giant Eagle pharmacy of an individual attempting to refill a prescription that contained codeine for a third time
AKRON_001160846	10/22/2014	Report of person attempting to get Opana with a fake prescription at a CVS pharmacy
AKRON_001162582	7/27/2012	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of "Drug Report," indicates multiple cases in which prescription opioids were seized
AKRON_001162639	3/7/2013	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of "Drug Report," indicates multiple cases in which prescription opioids were seized
AKRON_001163126	4/19/2011	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of "Drug Report," indicates a case in which prescription opioids were seized
AKRON_001163127	7/15/2011	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of "Drug Report,"

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Bates	Date	Summary
		indicates multiple cases in which prescription opioids were seized
AKRON_001164166	3/1/2013	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of "Drug Report," indicates multiple cases in which prescription opioids were seized
AKRON_001164167	3/1/2013	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of "Drug Report," indicates multiple cases in which prescription opioids were seized
AKRON_001164168	3/1/2013	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of "Drug Report," indicates multiple cases in which prescription opioids were seized
AKRON_001164169	3/1/2013	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of "Drug Report," indicates multiple cases in which prescription opioids were seized
AKRON_001164878	12/16/2014	Motions Order in case against Dr. Syed Zaidi who operated a pain management clinic in Solon, OH (Cuyahoga
AKRON_001168082	1/20/2017	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of "Drug Report," indicates a single case in which prescription opioids were seized
AKRON_001175294	6/2/2010	CAD Email with information on person, a Pharmacy Tech who, in the past year, stole approximately \$11,074.64 of Hydrocodone from CVS.
AKRON_001196727	3/7/2014	Report of Oxycodone prescription stolen from a private residence on 2/20/2014
AKRON_001196838	4/7/2014	Report of driver stopped and Percocet located under suspect's seat on 3/31/2014; a different report of stolen Oxycodone on 3/23/2014
AKRON_001197452	11/6/2014	Report of vehicle stop on 10/19/2014 in which officer found a morphine and an Oxycodone pill in person's wallet.
AKRON_001197600	1/23/2015	Report on 1/19/2015 of suspect found with Suboxone but does not have a prescription for it.

Bates	Date	Summary
AKRON_001208468	6/23/2009	CAD Email re: Report of person attempting to receive unprescribed Xanax and Vicodin from pharmacy
AKRON_001210410	4/30/2015	Email re: robbery of Rite Aid Pharmacy in Barberton. Suspect took a few bottles of Hydrocodone
AKRON_001242846, AKRON_001242849, AKRON_001242852	2/16/2010	Emails re: B&E at Highland Square Pharmacy; primary drug taken was Hydrocodone
AKRON_001243531	10/29/2010	Northeast Ohio Regional Fusion Center Weekly Crime/Intel Bulletin Contains report of Stow Police Department responding to a report of a CVS pharmacy robbery in which the suspect demanded the store's supply of 40mg Opana (@ AKRON_001243532)
AKRON_001247738	2/11/2010	Akron Police Department, Zone 1 Incidents: Report of B&E of Highland Square Pharmacy on 2/11/2010; Hydrocodone and Hydromorphone taken
AKRON_001247754	2/17/2010	Akron Police Department, Zone 1 Incidents: B&E at Highland Square Pharmacy; hydrocodone taken on 2/16/10
AKRON_001238728	1/4/2017	Report of theft of prescription opioid medication from a private residence during a party on 12/24/2016; another report of a theft of Oxycodone on 12/9/2016 during a move to a new apartment
AKRON_001242346	7/12/2016	Email from Maura McKinley to undisclosed recipients forwarding information about a case being worked by Twinsburg Detectives involving stolen doctor identities and DEA numbers being used to call in prometh-codeine syrup throughout Summit County. One suspect already in custody.
AKRON_001247550	7/28/2009 – 8/28/2009	Akron Police Department: FI Report: includes report of passenger in possession of Percocet
AKRON_001247770, AKRON_001247771	3/24/2010	Email and attached flyer re: two individuals who met officers to sell Oxycodone and one was found with pills on his person, the other was suspected in connection with Highland Square Pharmacy B&E
AKRON_001252089	10/23/2014	Email about fraudulent prescription orders for Phenergan with Codeine called into a CVS pharmacy in Copley, Ohio on several occasions

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Bates	Date	Summary
		using three different doctors' names and DEA tracking numbers
AKRON_001312600, AKRON_001312602, AKRON_001312604, AKRON_001312606, AKRON_001312607, AKRON_001312677, AKRON_001312678, AKRON_001312681, AKRON_001312683	9/26/2011	Emails between Patrick Leonard and Theodore Parren re: Dr. Harper
AKRON_001358604		Akron Police Department – City-wide Reports from the Weekend including report of unknown amount of Percocet on 2/24/2018; another report for theft of 20 dosage units of morphine on 2/23/2018; another report on 2/26/2018 traffic stop in which suspect had 4 Percocet in plain view during a traffic stop
AKRON_001363050	12/1/2017	Akron Police Department – City-wide Reports from the Weekend including report on 12/2/2017 report of Shamaar Gatlin in possession of Hydrocodone; report on 12/2/2017 of suspect who possessed an oxycodone pill; report on 12/2/2017 of unknown amount of stolen Oxycodone
AKRON_001363826	1/16/2018	Akron Police Department – City-wide Reports from the Weekend including report on 1/14/2018 of 40 units of stolen Oxycodone and report on 1/16/2018 of persons possessing a Suboxone pill
AKRON_001365547		Akron Police Department – City-wide Reports from the Weekend including report on 5/29/2018 of unknown suspect taking 36 dosage units of Oxycodone from the pharmacy without victim's permission; report on 5/20/2018 of unknown suspect taking victim's pill pouch including 20 dosage units of Oxycodone
AKRON_001367341		Akron Police Department – City-wide Reports from the Weekend including report on 3/18/2017 that persons possessed a dosage of hydrocodone
AKRON_001370814	5/3/2010	APD Zone 1 Incidents including report on 5/1/2010 that person was found to have 6 doses of Oxycodone wrapped in a dollar bill

Bates	Date	Summary
AKRON_001372468	6/7/2010	APD Zone 1 Incidents including report on 6/4/2010 that unknown suspect stole 89 Dilaudid pills
AKRON_001374052		APD Zone 1 Incidents including report on 6/27/2013 that person possessed three hydrocodone
AKRON_001376315	9/15/2014	APD Zone 1 Incidents including report on 9/15/2014 that person possessed Suboxone
AKRON_001375829	7/21/2014	APD Zone 1 Incidents including a report on 7/16/2014 in which person took 30 of the victims Oxycodone.
AKRON_001381132	4/7/2014	Report of incidents including 3/23/2014 report of the theft of Oxycodone pills from a private residence.
AKRON_001818322	8/19/2016	Email from a pain medicine doctor at Akron General Spine and Pain to Patrick Leonard re: patient selling prescription pain pills.
AKRON_001818328	4/9/2012	Email from Norton Police Dept. with Patrick Leonard copied re: Report from CVS Pharmacy about person calling in a Norco order by Dr. Harper who says he did not order the script.
AKRON_001312613	4/9/2009	Email from Gary Giorgio to Patrick Leonard re: person (doctor/prescription shopping). Giorgio says he would not have giving her Vicodin if he had the OARRS report in real time
AKRON_001312623	1/5/2010	Email to Patrick Leonard re: person (doctor/prescription shopping for Oxycodone)
AKRON_001312624	1/7/2010	Email from Hugh Schuckman re: person (doctor/prescription shopping for Percocet)
AKRON_001312626, AKRON_001312627, AKRON_001312629	2/17/2010	Email from Tom Miksch to Patrick Leonard re: Doctor Shopper, person with attached Ohio State Board of Pharmacy report showing his multiple prescriptions for various prescription opioids, drug report
AKRON_001312630	6/13/2010	Email from Dr. George Goldman to Patrick Leonard re: person; lied about amount of Percocet and Vicodin prescribed; OARRS shows doctor/script shopping
AKRON_001312631	6/30/2010	Email from Hugh Schuckman to Patrick Leonard re: doctor/script shopper.

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Bates	Date	Summary
AKRON_001312632	9/13/2010	Email from Detective Eric Roach to Patrick Leonard re: seeking information on potential script shopper.
AKRON_001312633	9/16/2010	Email from Hugh Schuckman to Patrick Leonard re: interesting OARRS report for person "from suboxone to multi scripts"
AKRON_001312634	10/5/2010	Email from Hugh Schuckman to Patrick Leonard re: strange guy. Apparent doctor/script shopping by person who is receiving multiple concurrent prescriptions for Percocet
AKRON_001312637	11/5/2010	Email from Hugh Schuckman to Patrick Leonard re: patient with 44 scripts from 16 providers with 8 pharmacies. Doctor/script shopping.
AKRON_001312638	11/26/2010	Email from a doctor to Patrick Leonard re: patient lying about Percocet. Doctor/script shopping
AKRON_001312639	12/28/2010	Email from Hugh Schuckman (Summa Health) re: person doctor/script shopping for methadone/morphine
AKRON_001312641	1/14/2011	Email from Hugh Schuckman to Patrick Leonard re: person, prior OD, doctor/script shopping, left when told no narcotic due to OARRS
AKRON_001312642	1/31/2011	Email from Hugh Schuckman to Patrick Leonard re: doctor/script shopping, multiple prescribers of Percocet concurrently
AKRON_001312643	2/4/2011	Email from Hugh Schuckman to Patrick Leonard re: person given 96 Percocet on a script for 40 pills
AKRON_001312644	2/23/2011	Email from Tom Miksch to Patrick Leonard about person who forged several oxycodone prescriptions in the name of Dr. Verlaine Blaser
AKRON_001312645	3/4/2011	Email from Hugh Schuckman to Patrick Leonard re: person suspected of doctor/script shopping.
AKRON_001312646	3/13/2011	Email from Hugh Schuckman to Patrick Leonard re: LOTS OF SCRIPTS for person, doctor/script shopping
AKRON_001312648	4/9/2011	Email from Hugh Schuckman to Patrick Leonard re: doctor/prescription shopping
AKRON_001312652	5/9/2011	Email from Hugh Schuckman to Patrick Leonard re: doctor/prescription shopping

Bates	Date	Summary
AKRON_001312655	5/19/2011	Email from Hugh Schuckman to Patrick Leonard re: doctor/script shopping
AKRON_001312656	6/7/2011	Email from Hugh Schuckman to Patrick Leonard re: person forgot he was on fentanyl patch, etc., doctor/script shopping
AKRON_001312657, AKRON_001312659	6/13/2011	Email from Hugh Schuckman to Patrick Leonard re: doctor/script shopping
AKRON_001312661	7/10/2011	Email from Hugh Schuckman to Patrick Leonard re: suspected doctor/script shopping, believes someone is forging scripts using her name
AKRON_001312662	8/15/2011	Email from Hugh Schuckman to Patrick Leonard re: doctor/script shopping
AKRON_000335953, AKRON_000335954, AKRON_000335955, AKRON_000335957, AKRON_000337869, AKRON_000337870, AKRON_000337871, AKRON_000370570, AKRON_000370572, AKRON_000370573, AKRON_000370634	5/28/15	<p>Dr. Gregory Ingram, who was an emergency room doctor at Akron General Medical Center, was indicted on 48 counts on Thursday.</p> <p>According to the indictment, Ingram wrote 46 prescriptions for oxycodone products for 11 different patients between November 2012 and October 2014. He met many of these people at strips clubs, and exchanged the scripts for money or sex acts, the indictment said.</p> <p>Federal investigators also accuse him of writing fraudulent prescriptions for Tramadol, a narcotic-like pain reliever, and Diazepam, which is used to treat anxiety, muscle spasms and alcohol withdrawal."</p>
SUMMIT_000037740	5/17/18	Email- story of Dr. Faye Jamali. She is a physician who became addicted to Opioids and is now in recovery.
SUMMIT_000038069, SUMMIT_000076849, SUMMIT_001009968		2010 Summit Excel Spreadsheet. Includes data re diverted pharmaceuticals, instances of doctor shopping, and law enforcement spending.
SUMMIT_000072538		2015 National Drug Threat Survey- Level of diversion for prescription drugs.
SUMMIT_000073031, SUMMIT_001002812	2/15/18	Email re press release. "Friday Feb 9 we were down in Mansfield had an arrest for possession of pills. This guy worked with us and helped with our case on Sunday Feb 11, 2018 with our Search

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Bates	Date	Summary
		Warrant in Mansfield. 400 pills oxycodone and 20 fentanyl patches. Search warrant was at 3571 N Main Street Mansfield, Ohio (This case is ref Doctor Frantz)."
SUMMIT_000074835, SUMMIT_001444018	4/5/17	Email- update on cases. "case with KNR is still being worked. There is currently a civil suit against KNR in the Summit County Courts. We are in contact with an Attorney out of Columbus with info from a current doctor working at office. FBI is also involved in this case. Working case looking to take that to grand jury shortly. Just opened a new case on it's a mental health Suboxone clinic. They have 5 locations. Main doctor is Dr. Ranjan."
SUMMIT_001010592, SUMMIT_001010776		Ohio Multijurisdictional Task Forces. January-June 2011 Performance Report Highlights. "Number of persons indicted for the following types of crimes: Forged/altered prescriptions: 138 Doctor shopping: 121 Healthcare fraud offense: 7 Theft of prescription drugs: 14 Sale of prescription drugs: 232 Possession of prescription drugs: 138 Other prescription drug scam offenses: 36" "Lake County Narcotics Agency The task force received an increase in the amount of complaints from doctor's offices reporting employees or medical assistants who illegally diverted prescription drugs. The task force believes this is a direct result of educational presentations." "During the second quarter of 2011, the drug task force conducted Operation Street Freedom 2011. The operation focused on serving arrest warrants upon individuals for possession and trafficking in heroin and pharmaceuticals, as well as doctor shopping. The operation was a huge success and yielded 26 arrests."
SUMMIT_001129868		Media Release "Summit County Sheriff's patrol deputies responded to Rite-Aid in the City of Green

Bates	Date	Summary
		<p>on September 3, 2009 at 7:20 p.m. for a female attempting to obtain Vicodin illegally. Deputies learned suspect, Age 31, of Barberton called in a prescription and the pharmacist became suspicious.</p> <p>Patrol deputies staked out the store and arrested the suspect when she arrived to pick up the prescription. She was charged with deception to obtain a dangerous drug. Deputies determined Ms. Strickland previously worked as a doctor's office and used the doctor's name and Drug Enforcement Agency number."</p>
AKRON_000326380	8/18/09	Email re Woman found guilty of illegally obtaining prescriptions by "doctor shopping".
SUMMIT_001444020	4/24/17	Email exchange re Sheriff's investigations. Mentions DEA case against doctor
AKRON_000368159	5/2010	Email Newsletter. "CLEVELAND POLICE DEPARTMENT – Starting in February 2010, numerous fraudulent prescriptions were successfully passed at local Cleveland pharmacies. The defendant, a Unit Secretary for Metro Hospital, admitted he found a prescription at work and stated he made several copies. The defendant used his personal computer to photo copy the prescription, which allowed him to manipulate its image. The subject obtained doctor's information and DEA numbers from an associate employed at a geriatric medical supplier. Names of doctors included on these forged prescriptions include, but are not limited to, Dr. Learned, Dr. Balina, Dr. Campbell, and Dr. Harrington."
AKRON_000368237, AKRON_000368246	11/5/10	Email exchange re doctor shopping. "dr harper wrote rx 10-29 for oxycodone 7.5/apap 325 #120 for celestial jones (we filled it) if he was aware she was a doctor shopper and wrote rx anyway can you use this info"
AKRON_000368263, AKRON_000368266	7/25/11	Email exchange re doctor shopping. "I ran [suspect's] OARRS again. For some reason, his wife shows up on his report. Looks like she is doctor shopping to. After I sorted out the Rx, since his arrest on 3/7, he has been to 14 different doctors.

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Bates	Date	Summary
		<p>6/28- received 30 oxycodone from Dr. McDonough</p> <p>6/27- received 60 oxycodone from Dr. Dr. Cullado</p> <p>6/24/11- received 120 Cheratussin (cough syrup with codeine) from Summa</p> <p>6/23- received 50 Oxycodone from Summa</p> <p>6/17 received 15 oxycodone from Summa</p> <p>6/9 received 15 oxycodone from Summa</p> <p>6/6 received 24 oxycodone from Dr. Vaughn</p> <p>6/3 received 6 oxycodone from Akron General</p> <p>5/27 received 60 tramadol from Summa</p> <p>4/25 received 60 tramadol from Summa</p> <p>4/16- received 8 hydrocodone from Summa</p> <p>4/12 received 60 tramadol from Summa</p> <p>3/19 received 25 oxycodone from Summa</p> <p>3/15 received 12 hydrocodone from Dr. Gallo</p> <p>During the same time period, per OARRS, his wife has been to different doctors 16 times.”</p>
AKRON_000368267	3/4/11	<p>Incident Report. “Suspect presented himself to the emergency department at St Thomas Hospital. Suspect provided false information to attending/prescribing physician to obtain controlled narcotic pain medication.</p> <p>Suspect has received controlled narcotic prescriptions from at least 58 different physicians in the past 12 months.”</p>
AKRON_000368577, AKRON_000368708	12/4/13	Email exchange re doctor shopping. “Gert forwarded this to me from a Doctor who works with ADM. Apparently there is a doctor out there offering “Suboxone Therapy.” It’s maybe the sketchiest business sign I’d ever seen.”
AKRON_000369321, AKRON_000369322, AKRON_000369323, AKRON_000369480	7/30/14	Email exchange re Dr. Harper news story. Dr. Harper and members of his staff were charged for improper prescribing practices. This resulted in the deaths of several of his patients.

Bates	Date	Summary
AKRON_000369993	3/16/16	Email re Deception to Obtain case. "Turned out the 75 year old doctor had written all of the scripts! I had a discussion with the doc and person is no longer a patient at that office. However i could not file any charges. I am sure that person is looking for a new doc to prescribe him the promethazine with codiene if he hasnt already found one."
AKRON_000370334	8/2013	Newsletter. person "obtained the Drug Enforcement Agency-issued prescription identification for a Cuyahoga Falls doctor. Using that number, [person] called in prescriptions for hydrocodone at various pharmacies throughout Summit County."
SUMMIT_001520527	12/18/12	Report of Investigation. A nurse was getting prescription opioids from multiple doctors. She was charged with Deception to Obtain.
AKRON_001126211	7/21/10	Email re individual filling bad prescriptions for Oxycodone.
AKRON_001126230	6/29/07	Email re individual attempting to get pain pills from doctor to sell.
AKRON_001126244	3/7/08	Email re Dr. Calvin Brown. "Dr. Brown was visited by person on 3/3/08 at his office on 1655 W. Market St. Ste. L. Person was asking for pain medication and Dr. Brown was willing to give him the meds until person was about to pay with a V.A. card. The Dr. then, supposedly, began to push person around. Once person told him that he was going to call the police, the Dr. then tried to give him a number of a guy that could give him the meds. Dr. Brown is known to have problems on S. Portage path."
AKRON_001126245	4/21/08	Email re individual seeking to fill a fraudulent prescription.

Plaintiff also identifies the following documents containing information responsive to this

Interrogatory pursuant to Federal Rule of Civil Procedure 33(d):

SUMMIT_000064914
SUMMIT_001131876
SUMMIT_000077148
SUMMIT_000077175
SUMMIT_000077336

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SUMMIT_001010174
SUMMIT_000077147
SUMMIT_000341980
AKRON_001165133
AKRON_001175095
AKRON_001176754
AKRON_001204632
AKRON_001243077
AKRON_000237864
AKRON_000368684
AKRON_000368686
AKRON_000368693
AKRON_000368705
AKRON_000368897
AKRON_000369261
AKRON_000369262
AKRON_000369715
AKRON_000004078
AKRON_000907525
MNK-T1_0002159629
MNK-T1_0002282670
MNK-T1_0004814570
MNK-T1_0002719188
MNK-T1_0007068789

Plaintiff reserves the right to supplement or amend its response as expert discovery commences, or to answer this interrogatory by producing responsive documents pursuant to Federal Rule of Civil Procedure 33(d). In addition, these issues will be the subject of fully-supported and detailed expert witness opinion(s).

Interrogatory No. 15:

Identify all communications prior to the filing of Plaintiff's initial Complaint between each Plaintiff or anyone acting on Plaintiff's behalf and any Manufacturer Defendant. Please include in your identification any communications in which, in words or substance, Plaintiff or anyone acting on Plaintiff's behalf requested information from such Manufacturer Defendant related to opioids or communicated complaints or concerns about such Defendant's acts or omissions related to

opioids. For each Manufacturer Defendant for which you cannot identify any communications between Plaintiff and that Manufacturer Defendant, please so state.

Response:

Plaintiff repeats and reasserts its prior objections and adopts its prior responses to this Interrogatory. Plaintiff objects to this Interrogatory as vague, overly broad and unduly burdensome to the extent it requests "all" communications prior to the filing of Plaintiff's "initial Complaint" between Plaintiff or anyone acting on Plaintiff's behalf and any Manufacturer Defendant. Plaintiff further objects to this Interrogatory in that it seeks information uniquely in the possession of the Manufacturer Defendants. Plaintiff objects to the extent the Interrogatory calls for irrelevant information or information protected by the attorney-client or work product privileges. Moreover, hundreds of depositions of fact witnesses have been taken of defense witnesses and bellwether Plaintiffs utilizing hundreds of exhibits. Millions of documents have been collected, produced and are being analyzed. The discovery performed to date, including depositions and document productions, provides details of voluminous "communications." It is not practicable to specifically identify each and every communication herein or every responsive document. Plaintiffs reserve the right to rely upon and introduce as evidence any and all deposition testimony and exhibits addressing this topic.

Subject to and without waiving all objections, Plaintiff identifies the following documents as containing responsive information pursuant to F.R.C.P. 33(d):

SUMMIT_000043688
SUMMIT_000113223
SUMMIT_000077532
SUMMIT_000077534
SUMMIT_000077535
SUMMIT_000077536
SUMMIT_000077537
SUMMIT_000077538

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SUMMIT_000077548
SUMMIT_000077551
SUMMIT_000124366
SUMMIT_000124373
SUMMIT_000124561
SUMMIT_000124564
SUMMIT_000124567
SUMMIT_000124571
SUMMIT_000124575
SUMMIT_001012229
SUMMIT_000124576
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SUMMIT_000124673
SUMMIT_000124675
SUMMIT_000124681
SUMMIT_000124682
SUMMIT_000291045
SUMMIT_000124688
SUMMIT_000128271
SUMMIT_000128272
SUMMIT_000128273
SUMMIT_000128284
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SUMMIT_000231193
SUMMIT_000231379
SUMMIT_000231733
SUMMIT_000232162
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SUMMIT_000277814
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SUMMIT_000360486
SUMMIT_000277876
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SUMMIT_000349255
SUMMIT_000349258
SUMMIT_000349260
SUMMIT_000278176
SUMMIT_000278177
SUMMIT_000272969
SUMMIT_000272975

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SUMMIT_000278182
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SUMMIT_000360528
SUMMIT_000360537
SUMMIT_000349275
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SUMMIT_000272989
SUMMIT_000272995
SUMMIT_000278218
SUMMIT_000278219
SUMMIT_000278220
SUMMIT_000278222
SUMMIT_000273000
SUMMIT_000273001
SUMMIT_000273002
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Plaintiff reserves the right to supplement or amend its response as expert discovery commences, and this issue may be the subject of fully-supported and detailed expert witness opinion(s).

Interrogatory No. 20:

Identify all “pill mills” (as that term is used in Plaintiff’s Second Amended Corrected Complaint) that exist or existed in Plaintiff’s jurisdiction. For each identification, state (i) which, if any, of the Manufacturer Defendant’s opioids that are or were prescribed at that “pill mill” in excessive quantities or inappropriately in any other way; (ii) other opioids not associated with any Manufacturer Defendant that are or were prescribed at that “pill mill” in excessive quantities or inappropriately in any other way; (iii) when Plaintiff first learned of the existence of each “pill mill,” (iv) all actions Plaintiff or those acting on Plaintiff’s behalf has taken to restrict, shut down,

curtail, or otherwise reduce the harmful effects of that “pill mill”, and (v) whether the “pill mill” is currently operating in any form.

Response:

Plaintiff repeats and reasserts its prior objections and adopts its prior responses to this Interrogatory. Plaintiff objects to this Interrogatory as vague, overly broad and unduly burdensome to the extent it requests “all” pill mills and “which if any, of the Manufacturer Defendant’s opioids that are or were prescribed at that ‘pill mill’ in excessive quantities or inappropriately in any other way.” Plaintiff further objects to this Interrogatory in that it seeks information already in the possession of the Manufacturer Defendants and third parties of which Plaintiff may not be aware, much less have possession or control over, and thus seeks to impose an undue burden and unnecessary expense on Plaintiff.

Plaintiff incorporates by reference its responses to Distributor Defendants’ Interrogatories 2, 3, 8, 14 & 15; Manufacturer Defendants’ Interrogatories 10 & 13; and National Retail Pharmacy Defendants’ Interrogatories 2, 3 & 4. Plaintiff further incorporates by reference its “Responses to the Amended and Clarified Discovery Ruling 12 Supplemental Interrogatory Issued to Plaintiffs” dated January 25, 2019 (Pharmacy Interrogatory No. 7 and Distributor Interrogatory No. 23); “Responses to Supplemental Interrogatory Issued in Discovery Ruling 12 to Plaintiffs” dated January 11, 2019 (Pharmacy Interrogatory No. 7 and Distributor Interrogatory No. 23); “Supplemental Amended Responses and Objections to the Manufacturer Defendants’ First Set of Interrogatories, Submitted Pursuant to Discover Ruling No. 13” dated December 31, 2018 (Manufacturer Interrogatory No. 6); “Supplemental Objections and Responses to Manufacturer Defendants’ Interrogatory Nos. 27/28” dated December 21, 2018; “Fourth Amended Responses and Objections to Manufacturer Defendants’ First Set of Interrogatories” dated December 14, 2018 (Manufacturer Interrogatory Nos. 6 & 10); “Supplemental Responses & Objections to

Reformulated Suspicious Order Interrogatory Served by Manufacturer Defendants” dated November 27, 2018 (Manufacturer Interrogatory No. 27); “Amended Responses and Objections to the Manufacturer Defendants’ First Set of Interrogatories and the National Retail Pharmacy Defendants’ First Set of Interrogatories” dated November 2, 2018 (Manufacturer Interrogatory No. 10 and Pharmacy Interrogatory Nos. 2 & 3); “Amended Responses and Objections to the National Retail Pharmacy Defendants First Set of Interrogatories and Distributor Defendants’ Fourth Set of Interrogatories” dated October 31, 2018 (Distributor Interrogatory No. 23 and Pharmacy Interrogatory No. 7); “Responses and Objections to Distributor Defendants’ Fourth Set of Interrogatories” dated August 31, 2018 (Distributor Interrogatory Nos. 23 & 29); “First Amended Responses and Objections to Distributor Defendants’ Third Set of Interrogatories” dated August 13, 2018 (Distributor Interrogatory Nos. 16 & 17); and “Initial Responses and Objections to Manufacturer Defendants’ Second Set of Interrogatories” dated July 5, 2018 (Manufacturer Interrogatory No. 27).

Plaintiff further responds that local prescriber- and patient-level data is in the possession of the data mining companies frequently used by Defendants to monitor such information. These companies include, but are not limited to, IMS Health, QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and PRA Health Science. Pursuant to comments from the U.S. Department of Justice Drug Enforcement Administration (“DEA”), Defendants also compiled “know your customer” questionnaires and files that contain such data and information.

Subject to and without waiving all objections, Plaintiff further answers as follows:

Dr. Adolph Harper, Jr. was a licensed physician in Akron, Ohio who operated a “pill mill.” Although Harper’s specialty was obstetrics and gynecology, he primarily treated patients for pain

during his last several years as a physician. In May 2012, Harper surrendered his medical license, in lieu of formal disciplinary proceedings, after local, federal and state agencies launched an investigation into his practice.

As discussed in more detail below, Harper was influenced by marketing from opioid manufacturers, including Purdue Pharma and Endo Pharmaceuticals. Beginning in the late 1990s, Purdue Pharma sales representatives positioned OxyContin as a safe opioid and encouraged the gynecologist to titrate to high doses of OxyContin when treating chronic pain patients. A decade later, Harper was prioritized as a target for marketing by Endo Pharmaceuticals, and he became a high prescriber of Opana ER. Eventually, the Endo sales representative assigned to Harper grew deeply uncomfortable with Harper and requested that Endo remove the doctor from his sales call plan. However, the sales representative's manager mandated that he continue to promote Opana ER to Harper, despite clear signs that the doctor was operating a pill mill.

The Department of Justice's news release regarding Harper's sentencing indicated that Harper distributed "hundreds of thousands of doses of prescription medications – including OxyContin, Percocet, Roxicet, Opana and others – from his medical offices in Akron." <https://www.justice.gov/usao-ndoh/pr/akron-doctor-sentenced-10-years-prison-illegally-prescribing-painkillers-even-after>. At least eight of Adolph Harper's patients ultimately died as a result of drug overdoses according to law enforcement.

On March 25, 2014, federal prosecutors indicted Adolph Harper, Jr. and three of his employees on charges that included conspiring to traffic pharmaceutical drugs, drug trafficking, and health care fraud. Facts from Harper's case are available in the criminal indictment, sentencing memoranda and a post-sentencing pro se motion filed by Harper. Department of Justice press releases relating to the case can be found here: <https://www.justice.gov/usao-ndoh/pr/akron-doctor-pleads-guilty-illegally-prescribing-painkillers> <https://www.justice.gov/usao-ndoh/pr/akron-doctor-sentenced-10-years-prison-illegally-prescribing-painkillers-even-after>

[ndoh/pr/akron-doctor-sentenced-10-years-prison-illegally-prescribing-painkillers-even-after.](#)

Harper's co-defendants included Adria Harper (office receptionist and Harper's daughter), Patricia Laughman (office receptionist) and Tequilla Berry (assistant). Prosecutors maintained that the defendants intentionally distributed Schedule II and Schedule III opioids (including oxycodone, oxymorphone, methadone and hydrocodone)

According to the indictment, many of Harper's patients exhibited clear signs of addiction. Patients received prescriptions for opioids without being properly examined by Harper, and often without seeing him at all. Harper continued to distribute prescriptions for controlled substances after he learned that some of his customers had died as a result of drug overdose. Additionally, his employees handed out pre-signed prescriptions to these customers when Harper was out of the office. The indictment also revealed that Adria Harper used her father's prescription pad to write herself prescriptions for Percocet. Similarly, Patricia Laughman used the doctor's prescription pad to write herself prescriptions for Percocet, and oxycodone. Adria Harper also attended speaker programs for Opana (February 2010) and Purdue (November 2013). PPLPC014000229312; ENDO-OPIOID_MDL-00932951. She is also listed as recipient of eight meals provided by Endo between 2010 and 2012. ENDO-OPIOID_MDL-00673563.

On October 20, 2014, Adolph Harper pleaded guilty to one count of conspiracy to traffic drugs, four counts of health care fraud and sixteen counts of drug trafficking. He was subsequently sentenced to ten years imprisonment, followed by five years of supervised release, and ordered to pay \$417,364 in restitution. Harper is currently incarcerated. Adria Harper pleaded guilty to one count of conspiracy to traffic drugs and 25 counts of drug trafficking; she was sentenced to 51 months in prison. Patricia Laughman pleaded guilty to one count of conspiracy to traffic drugs and fourteen counts of drug trafficking; she was sentenced to 15 months in prison. Tequilla Berry

pleaded guilty to one count of conspiracy to traffic drugs and seven counts of drug trafficking; she was sentenced to five years of probation.

In the sentencing memorandum submitted to the court following Harper's guilty plea, prosecutors described an office environment that should have alarmed any sales representative or agent of the Defendants who visited Harper's office: "The atmosphere of Harper's office, like his prescribing practices, was also more akin to street-level drug trafficking operation rather than a medical office. Harper's customers often waited for hours to see Harper, and many of these customers exhibited behavior consistent with drug abuse. Witnesses reported seeing customers passed out in the hallway and office while waiting to see Harper, or vomiting or urinating on the floor in the waiting room. Customers were also combative and aggressive with Harper's staff members if there was any delay in receiving their drugs."

Harper's dangerous prescribing habits and the disturbing atmosphere at his office were so open and obvious the defendants knew or should have known his practice was operating as a pill mill. *See* PLTF_2804_000004563-4566. Additionally, Harper had a relationship with Endo sales representative Anthony Slimon.

By early 2010, Harper was already treating a fair number of patients for chronic pain, but the majority of the individuals he saw were female gynecology patients. Over time, his pain management practice grew dramatically, and by the time the office was shut down, Harper was seeing hundreds of pain patients, both male and female.

Dr. Harper's office was usually packed with patients, many of whom appeared intoxicated. Often people had to stand in the waiting room because there were not enough seats. In the mornings, many people waited outside for the office to open. The patients usually had to wait several hours to see Harper. The office was "very rowdy," and patients often become belligerent with one another in the waiting room or combative with the staff. Fights broke out among the

patients “all the time.” On the other side of the spectrum, many patients were overly sedated and fell asleep in the waiting room. Occasionally, patients passed out on the floor.

Ramona Harrison was employed as a receptionist at the office of Dr. Adolph Harper from 2010 through January 2012. *See* PLTF_2804_000004563-4566. Her responsibilities included answering the phones, scheduling patient appointments and calling in prescriptions to pharmacies.

Dr. Harper frequently prescribed Opana, OxyContin, oxycodone, Percocet and Vicodin. The drugs he prescribed often depended on the patient’s insurance coverage. Because Ohio Medicaid and many insurance companies often did not cover branded opioids like Opana and OxyContin, many painkillers Harper prescribed were generic. Many patients, however, paid cash for branded drugs like Opana and OxyContin.

Purdue’s sales representative call history for Harper, however, indicated that the company began to cultivate the doctor as a prescriber of high dose OxyContin to treat chronic pain as far back as the late 1990s. From 1997 through 2001, Harper was called upon at least 368 times by Purdue sales representatives Todd Restivo, Lisa Thomas, Gina Price, and Kimberly Moser. The call notes from these visits to Harper’s office show that sale representatives regularly encouraged the gynecologist to consider prescribing OxyContin as an alternative to short-acting drugs like Percocet, Vicodin and Lortab to treat both acute and chronic pain. PPLPMDL0030005334

According to their notes, sales representatives presented OxyContin to Harper as a safe and stable opioid, and conveyed to him that OxyContin could improve a patient’s “quality of life” and had “lower abuse potential” than short-acting opioids. For example, on December 9, 1997, sales representative Todd Restivo met with Harper and “used the [package insert] to show delivery system, hit acute and chronic pain management, show safety, lack of abuse potential, less dosing with improved quality of life.” PPLPMDL0030005334

On November 1, 2000, another sales representative, Lisa Thomas, reported the following after her meeting with Harper: "use pretty much oxy. Has a few patients on 80 mg introed the 160 mg. didn't have much interest in it." On February 26, 2001, Thomas wrote that Harper was "very busy, wants to discuss oxy abuse. Uses a lot of 40's scheduled lunch to get more time with him." After her next meeting with Harper on March 14, 2001, Thomas wrote that they "went over documentation kit because of oxy abuse lately. Need to discuss addiction/ and other terminology. Seems to think his patients like oxy because they are hooked." PPLPMDL0030005334

According to the call history, Thomas met with Harper on ten occasions between August 2000 and June 2001. During the interview, Thomas said she did not recall marketing OxyContin to any gynecologist and she did not recognize the name Adolph Harper. Thomas marketed OxyContin as an alternative to short-acting opioids that would help improve the quality of life of pain patients. She encouraged doctors to titrate up the dosage of OxyContin if the lower dose was not resulting in satisfactory pain relief, and she often recommended titration as an alternative to dosing OxyContin more than twice a day.

Thomas cautioned doctors who might be concerned that their patients could become dependent on OxyContin that "dependency" was not the same thing as "addiction." She often used the analogy of coffee/caffeine, explaining that many people are "dependent" on caffeine and might suffer withdrawal symptoms if they stopped taking caffeine, but that did not mean they were addicts. She used the coffee example to illustrate to physicians that there was a difference between becoming addicted to something and becoming physically dependent on something.

Another Purdue sales representative, Kimberly Moser Li, called on Harper's office on 21 occasions between October 1, 2002 and June 7, 2004. Li's call notes from July 30, 2003 indicated: "Signed up for tamper resistant prescription pads. Asked where and why he uses Oxycontin. Patients with chronic pain. He likes it for smooth blood levels."

Li stated that she marketed extended release OxyContin for pain and told physicians that the drug was a better alternative to short-acting opioids because it provided more “stabilization,” “fewer peaks and valleys,” and because it did not contain acetaminophen. Li also implied to physicians that OxyContin was less prone to diversion because a patient on the drug would only be taking two pills a day. Alternatively, patients on short-acting opioids were prescribed a supply of drugs to take one or two pills every four to six hours “as needed.” According to Li, physicians might therefore be prescribing more short-acting pills than was necessary, which increased the potential for diversion. In contrast, the Q12 dosing of extended release OxyContin meant the patient would be prescribed far fewer pills and a more consistent pill regimen.

Purdue sales representatives marketed OxyContin to Adolph Harper. In 2001, Purdue spent \$410,000 on two new marketing materials targeted to gynecologists: (1) *OB/GYN Case Study Flashcard* – “A case study series which focuses on the most prevalent pain conditions in gynecology.” (2) *OB/GYN Consensus Panel Symposium on Pain*– “A roundtable consensus panel of thought leaders on the topic of pain in the female patient. Includes production for enduring educational materials.” [PPLPC009000026013; PPLPMDL0030005327; ACTAVIS0703353; ENDO-OPIOID_MDL-04041455].

Harper continued to prescribe OxyContin after Purdue ended its sales calls. According to prescription data compiled by Actavis as part of its Kadian sales campaign, Harper wrote 442 prescriptions for OxyContin between June 2011 and May 2012, which was his last year practicing as a physician before he surrendered his medical license. Purdue’s list of annual prescriptions of Purdue products shows that he wrote 1,277 Purdue prescriptions in 2011.

Adolph Harper was considered to be a high priority physician for Endo Pharmaceuticals and the company successfully influenced him to prescribe Opana ER to patients. Endo aggressively began marketing to Harper as early as 2008. Sales representative Stacey Orbovich

included Harper on her Opana ER Business Plan for the year in a document dated February 19, 2008. She wrote: "Continue hyper-targeting Dr. Harper more aggressively so that he may hopefully begin to understand the value Opana ER may provide his patients. Continue scheduling lunches. Get Adria his [office manager] to do prior auth for Caresource, Unison and Buckeye patients before surgery so he can give them Opana 5mg instead of Percocet 5/325 for PRN [as needed]." According to data compiled by the Hibbert Group for Endo, in August and September 2008, there were two redemptions for Harper's patients for the Opana ER Instant Savings Card program. EPI001032820.

In addition to office visits from sales representatives, Endo also targeted Harper in a supplemental mail marketing campaign as part of the company's Ten Key State Initiative, according to an email circulated to regional directors on September 15, 2008. ENDO-OPIOID_MDL-00699405 & ENDO-OPIOID_MDL-00699406. Orbovich hosted a dinner program for Harper and a few other physicians at Harper's office on February 22, 2010. The program was titled "The Role of OPANA® ER (oxymorphone HCl) in the Management of Moderate to Severe Chronic Pain" ENDO-OPIOID_MDL-04028550 & ENDO_DATA-OPIOID_MDL-00000043. Previously, on April 28, 2009, Orbovich asked her colleague, Lisa Geissinger, to invite Adolph Harper to a dinner program Geissinger scheduled for June 17, 2009. Of the program, Geissinger wrote: "This will be an excellent educational program: [Speaker] Dr. Thomas is highly recommended for his pharmacology and practical experience with Opana. Dr. Thomas is a specialist on safe opioid use, including addiction issues." [ENDO-OPIOID_MDL-06147658] Following the program, Geissinger emailed Orbovich that she was 99% sure that Harper had not attended the program [ENDO-OPIOID_MDL-06147690].

By the time Harper surrendered his license in May 2012, he was a high prescriber of Opana ER. According to prescription data compiled by Actavis, Harper wrote 860 prescriptions for Opana ER between June 2011 and May 2012. ACTAVIS0703353.

Endo Pharmaceuticals sales representative Anthony Slimon also called on Adolph Harper. He worked for Endo from November 2007 through October 2012, covering a territory in Ohio that included Akron, Canton, Steubenville and St. Clairesville. Slimon said that at some point relatively early on during his tenure at Endo – around 2009 – Adolph Harper appeared on his call plan, which consisted of physicians who were already comfortable prescribing opioids.

On a draft Power Point presentation circulated on January 11, 2011, Endo listed Dr. Harper as one of their “hyper targets” for Opana ER. Based on the data obtained from Actavis, Dr. Harper was a high prescriber of Opana ER during the last year that he practiced. ENDO-OPIOID_MDL-04194211.

Dr. Harper’s name appeared on an Endo spreadsheet from April 20, 2012 of prescribers removed from territory and district goals, which included removals for compliance-related reasons. The justification for Dr. Harper’s removal was listed as “License is being investigated and has made local news due to questionable actions.” ENDO-OPIOID_md1-02816744 & END00746489.

Dr. Harper’s daughter, Adria Harper, assisted in distributing hundreds of thousands of doses of prescription medications including OxyContin, Percocet, Roxicet, Opana and others between 2009 and 2012. Records show Adria Harper attended at least two Endo speaker programs between 2010 and 2013, and Endo made payments to Adria for meals and other items between December 2010 and January 2012. (PPLPC014000229312, ENDO-OPIOID_MDL-00932951, ENDO-OPIOID_MD-00673563)

Sales call history documentation indicated that Cephalon sales representative David Vukovich called on Adolph Harper on 24 occasions between September 2004 and May 2005 to

market the fentanyl lollipop Actiq. After his initial call to the doctor on September 22, 2004, Vukovich notated: "1st call-discussed actiq for btcp [breakthrough cancer pain]. At office 2 hrs. great discussion. Sees a definite need for actiq." TEVA_MDL_A_02416207. Dr. Harper was also listed as a registered attendee for a "Chronic Pain program" hosted by Cephalon in Akron, Ohio on April 29, 2005. TEVA_MDL_A_10029498.

Vukovich was employed at Cephalon from November 2003 through March 2007, covering the Akron, Ohio area. Although Actiq was only indicated to treat cancer pain, Vukovich was assigned to market the drug to high prescribers of opioids, including pain specialists and primary care doctors who did not treat cancer patients.

According to an Actavis spreadsheet that compiled 12 months of prescription data from June 2011 through May 2012, Harper was targeted by the company for Kadian, but he was not listed as having written any prescriptions for the branded morphine drug. He did write 71 prescriptions for generic morphine sulphate ER during this period. However, years earlier – on December 1, 2003 – Purdue sales representative Kimberly Moser Li recorded the following in her call notes about Harper: "He said that Kadian and Avinza [a morphine drug manufactured by Elan Corp.] reps. have been coming in a lot lately with free coupons for new patient starts. He said they both push once a day dosing and less potential for abuse. I asked what he thought. He said they don't work as well as Oxycontin but the free coupons help for patients that don't have insurance." PPLPMDL0030005334.

A spreadsheet dated July 31, 2009 recorded 12 sales calls that Janssen sales representative Michelle Bronner paid to Harper between February and July 2009. JAN-OH-00009302. Concerning their meeting on July 10, 2009, Bronner recorded: "Overview of Nucynta – he mentioned that he would try Nucynta next week, with patients at the hosp. He was concerned about tiered coverage and he saw the adv of Nucynta vs percocet." Harper was also listed as a target for

Bronner in regard to the Cleveland District Nucynta Sales Contest. JAN-OH-00006800. As part of the contest, sales representatives were challenged to pick 20 potential Nucynta prescribers and “gain a commitment to use Nucynta for the appropriate patient during the months of August and September.” Additionally, Harper was listed on a spreadsheet circulated by Kevin Becker, a Covidien district manager, on July 5, 2011 showing that Harper was number seven on a list of top Ohio Medicaid prescribers “in the Narcotic Market” with 1,286 total prescriptions. Harper was assigned to Covidien sales representative Steven Sage and ranked as a seven decile prescriber. The spreadsheet indicated that Sage had made seven “contact calls” to Harper. MNK-T1_0005653984 & MNK-T1_0005653985.

McKesson emails disclose that in September and October 2011, Rite Aid store 3182 in Akron, Ohio requested that McKesson increase its threshold on oxycodone by 15 percent on two occasions because of “increased activity from a local pain mgmt. doctor,” Adolph Harper. MCKMDL00632908 & MCKMDL00626683; Deposition of Sophia Lai Novack. It appears McKesson approved the September 2011 request, but denied the October 2011 request. On October 26, 2011, McKesson account manager Jenna Nichols noted that the store had previously “received an increase on the oxycodone base code of 4000 doses 10 days ago. After another 15% increase, this will result in a 33% increase in the same month.” Dave Gustin, a regulatory employee at McKesson, corrected Nichols: “Actually it was less than 40 days ago. . . But it still is an issue as we consider 90 days the least amount of time between increases for just ‘business growth’ and even then the increases should be nominal.” MCKMDL00627671.

On December 7, 2010, a Cardinal Health investigator, Timothy Dunham, completed a QRA site visit to Medicine Shoppe #1065 in Norton, Ohio. Adolph Harper was identified as one of the pharmacy’s top five prescribers of controlled substances. CAH_MDL2804_0000578. According

to the investigator's case notes, the owner/pharmacist-in-charge at the store had concerns about Harper and "contacted the Ohio Medical Board as well as the DEA on multiple occasions."

According to Harper's sentencing memorandum submitted by prosecutors, several Akron-area pharmacies began refusing to fill Adolph Harper's prescriptions because of the dangerous quantities and drug combinations the doctor frequently wrote. In response, Harper and his staff then posted a list in the medical office of pharmacies that were likely to fill his prescriptions.

Prescription data compiled by Actavis for the promotion of Kadian disclosed that between June 2011 and May 2012 (Harper's last year in practice), he wrote 2,344 prescriptions oxycodone HCL, 860 prescriptions for Opana ER, 442 prescriptions for OxyContin, 71 prescriptions for generic morphine sulphate ER and two prescriptions for oxymorphone HCL. ACTAVIS0703353

Documents from Harper's criminal case outlined 12 patients who were inappropriately prescribed opioids by the physician's office. According to the sentencing memorandum prosecutors submitted to the court following Harper's guilty plea: "Accounting for only the controlled substances that Harper prescribed to these twelve customers, the amount of drugs distributed by Harper during the course of the conspiracy and/or directly attributable to his actions and reasonably foreseeable within the conspiracy was at least 469.57 grams of oxycodone, 143.28 grams of oxymorphone, 25.776 grams of alprazolam, 30.48 grams of methadone, 9 grams of amphetamines, and 0.85 grams of zolpidem." AKRON_000369480.

At least eight of Harper's customers died of overdose-related causes, including some who "died within weeks, some even within days, of receiving a prescription from Harper." Prosecutors identified these eight individuals only by their initials in court filings. *See* SUMMIT_000059321, SUMMIT_000059321, SUMMIT_000059413 & AKRON_000368261.

In December 2014, a former Summit County family-medicine doctor named Brian Heim pled guilty to conspiracy to distribute controlled substances and 20 counts of distribution of

controlled substances. Dr. Heim had a history of substance use, as evident from his September 19, 1998 Consent Agreement with the State Medical Board of Ohio after his license was suspended due to habitual use of drugs and alcohol. PPLPMDL0030005427 In Summit client production, Heim appears in a Medical Examiner reports as prescribing Oxy to a deceased patient. SUMMIT_HC_000025584 The patient's death date was February 21, 2009 and Dr. Heim filled an Oxy prescription three days earlier. SUMMIT_HC_000025571-5573, SUMMIT_HC_000025582-5583, SUMMIT_HC_000025600, SUMMIT_HC_000025627. From August 2011 through October 2012, Heim distributed thousands of doses of prescription painkillers to his customers without a legitimate medical purpose, including more than 30,000 tablets of Oxycodone, OxyContin and Opana. OHIOMEDBOARD000000062.

Call Notes from 1994 to 2005 show Dr. Heim being regularly called upon by Purdue sales representative Todd Restivo. PPLPMDL0030005497, PPLPMDL0080000001 Several representative call note excerpts follow:

9/25/03 He is treating more older patients with chronic opioids, usually 40 yrs and older. Talked about how he evaluates patients, no patient will get opioids for chronic use unless has documented pathology. AHCPR guidelines oral route is preferred and transdermal for stable pain. Uniphyll and Senokot availability.

10/22/03 Ongoing assessment forms, adding functionality along with numerical values to pain. Pain management CD ROM kit. Discussed appropriate pts for OxyContin per PI and indication. AHCPR guidelines oral route preferred and transdermal for stable pain.

1/9/04 OxyContin talked about initiation of therapy section for 10mg q12h after NSAIDS. He said using more on pts that have been on short acting opioids, so hit conversion factors in PI along with giving a titration guide.

In an April 2008 email, "The husband explained that his wife's current doctor is no longer able/willing to prescribe her medication OxyContin. He wanted to make sure we were aware of his wife's former physician, Dr. Brian Heim in Copley, OH and past actions taken against him by State Medical Board of OH." PPLPMDL0030005508.

From January 2010 through December 2011, Dr. Heim was listed as the 11th top prescriber of Oxycodone/APAP in the W103 – Akron, OH Territory. ACTAVIS0925276.

Purdue call notes indicate that his main sales representative was Cathleen Lapmardo. A few call notes detailing follow:

5/24/11 I explained Butrans in depth over a lunch appt utilizing the FPI. Dr. Heim felt very comfortable with the molecule Buprenorphine and said there were many patients in his practice that would benefit from therapy. He said he would definitely start to incorporate Butrans therapy into his practice. He said he felt confident initiating therapy to both opioid naive and opioid experienced patients.

6/11/12 Spoke to Dana about the OxyContin and Butrans managed care coverage updates. Asked Dana who does the call backs and PA's. Spoke to Jen about the OxyContin coverage. I asked her if they have Medical Mutual prescription insurance patients and Anthem Sr Advantage. Jen said they have a good amount of both. Showed OxyContin managed care matrix and highlighted coverage on appropriate plans. Gave ESI Butrans flashcard and discussed overall coverage.

A March 7, 2013 Purdue email from Joan Zooper to Barry Chudakoff, Clifford Reich, and Maurice Mulcahy (copying Cramer, Petty, Fisher, Laura Watson, Tim Richard, Janet Jiminez and ADDDirection@pharma.com) admits, “[s]ales representatives should not call on Dr. Brian Heim.” PPLPMDL0030005410

In a January 2011 Nucynta Speaker Direct Physician Invitation Recommendations, Brian Heim is one of five listed in Ohio. JAN-MS-03007566 For July/August 2012-Heim was listed in Janssen Nucynta Brand CP List. JAN00124876

An October 2007 email chain regarding Dr. Brian Heim states:

Buckeye is one of the major plans in my [Stacey Orbovich-Endo Sales Rep] territory, which is not covering Opana and Opana ER with prior authorization. I have tried to get several physicians with high potential for oxymorphone to prescribe, but have had little success because of Buckeye not approving it. Today I went in to follow up with Dr. Brian Heim on a severe chronic low back pain patient who was denied by Buckeye. He was told that Buckeye offers 11 different treatment options for the patient and oxymorphone is not one of them. The patient had previously been on 8 of the recommended meds and was told that she would not be able to go back to Oxycontin, her current med, if she switches to a new option because of failure. The patient was not able to switch and was very disappointed

because she wants to switch to something new. Dr. Heim's top plans are Buckeye, Sumacare and CVS - Caremark. This is frustrating to the physician and discourages him from prescribing oxymorphone again because of the callbacks. There is a lot of business I'm missing out on because he is one of the top family practice pain physicians in my territory. He's a descale [sic] 7 and averages 600 Oxycontin prescriptions this year. He is willing to fill out prior auth forms and stocking is not an issue. I'm not sure what else to do for Dr. Heim at this point. The patients can't afford to pay cash for Opana ER even with the rebate. Dr. William Kerek, Dr. Richard Pitt, Dr. Ben Prestegaard, and Dr. Benson Bonyo have all tried prescribing Opana ER for their Buckeye patients and did prior auth, and were denied, so they have decided to not try it on any more patients until coverage gets better. ENDO-OPIOID_MDL-04027937.

In August 2011, Dr. Heim attended a Logistic Innovations Purdue Speaker Program Dinner Meeting. PPLPC014000151407. Heim was also listed in an April 2012 Opana ER call plan. ENDO-CHI_LIT-00108866. He was also a 2014 Opana ER target; and a 2014 Top Opana ER Writer on a list containing 1,664 prescribers. ENO-CHI_LIT-00181945, ENDO-CHI_LIT-00200052 In an October 2012 email regarding a territory update, "There have been some changes in the footprint landscape recently that I wanted to make you aware of. Several of our Opana ER target have lost their licenses: Dr. Norm Lefkovitz and Dr. Brian Heim (in process)." ENDO-OPIOID_MDL-04198292

In a May 2015 Presentation titled *Heroin Identification, Trends, and OD Death Investigations* presented by Akron PD Narcotics Unit (Det. Mike Schmidt and Det. Tim Harvey), Dr. Brian Heim along with Dr. Adolph Harper are referenced. AKRON_001165133. Heim was sentenced to more than five years in federal prison in March 2015.

Dr. Charles Njoku with People's Family Medical Center in Akron and Columbus, Ohio and his office manager were charged with prescribing medicine without a legitimate medical purpose in January 2010. Purdue called on Dr. Njoku ninety-two times between 1994 and 2005, noting that he used OxyContin for a number of varying pain ailments until mid-2001 when Dr.

Njoku states that there are "too many problems" with OxyContin due to abuse and diversion.

PPLPMDL0080000001, PPLPMDL0020000001 A few notable call notes follow:

3/16/99 Dr is starting to use oxy for post op pain, found out that most of opioids are being used for low back pain. He has a lot of abuse potential pts and he gives the pts what they want.

7/18/00 why does he still give patients vicodin and percocet for acute pain vs oxycontin? habit, he gives the patients what they want to start with, i went over the Marcus reprint and showed him the advantage of long acting opioids over short acting. With short acting patients experience more sedation and euphoria.

10/20/00 abuse and street value of opioids is a concern. Uses percocet and Vicodin. Patients are asking for oxycontin by name now. Went over the oxy PI vs short acting opioids. Oxy q12h better pain control.

12/12/00 he is using oxycontin for chronic musculoskeletal pain. Talked about the street value of oxycontin, in his Arlington office he says that everyone is asking for it. This has not discouraged him from writing for the right person, but he is not using it for short term pain. I went over oxycontin and concentrated on the pt in pain. I gave him the CD for assessment tools and opioid contract.

02/20/01 complaints are that patients taking OxyContin are selling the medication and not taking it, said pts were given urine screens and oxycodone was not showing up. Once the patients were getting their Oxy scripts and the not showing up for their MRI's. Discussed using OxyContin for the right patient and he did say that it worked for a lot of his patients, so he did write a 40mg tab script for an older woman with Osteochondritis, so set up a lunch and he said will be more selective in patients getting OxyContin.

5/25/01 concern with patients selling OxyContin, not sure of the pain patients or pts that may be diverting.

07/09/01 He said he has stopped writing OxyContin because of abuse and diversion.

08/01 Not using OxyContin, too many problem, pts come in asking for it and has had some patients sell OxyContin on the street.

12/15/05 Went over coupon program and D.A.W campaign with the physician. He is doing a lot of pain management and has many of his patients on OxyContin. Was a quick call.

Call notes from 2006-2017 show Barry Chudakoff and Brian Backiewicz as Njoku's main representatives. PPLPMDL0020000001. For example:

5/5/06 Dr. said he has no problem prescribing OxyContin. He feels it is a good medication that help a lot of people when used appropriately. Discussed using low-dose OxyContin as a starting dose for appropriate patients according to our PI. Dr. said the only time he usually does not start a patient on OxyContin is when he feels they may abuse the medication. Also discussed the use of Senokot-S for opioid induced constipation.

4/22/08 Dr Njoku said he has problems with some insurers and the brand. I asked what insurers and Dr said they are Medicaid Part D plans. I went over private insurers and the use of discount cards. Dr said he has used and will use because they are helpful. I went over using new strengths to titrate.

Endo's February 2008 Sales Representative Business Plan identifies Dr. Njoku as an "Opana ER Top 20;" he was also listed as a "Project Target" and invited to lunches once a month. ENDO00747477. A 2009 Actavis target doctor spreadsheet lists Dr. Njoku. ACTAVIS1029157. Finally, an October 2010 Mallinckrodt sales representative call spreadsheet indicated that Dr. Njoku had been called twelve times YTD. MNK-T1_0000248810.

Massachusetts chemist Bin Wang was arrested, charged, and pled guilty to purchasing synthetic opioids from China and then distributing them within Ohio and the United States. Leroy Steele and Sabrina Robinson, an Akron couple, were charged in relation to the death of an Akron man who had overdosed on synthetic opioids that Steele had purchased from China. They were sentenced to prison for 20 and 10 years, respectively. Ryan Sumlin also sold some of the synthetic opioids from Wang to an Akron woman, who fatally overdosed in March 2015.⁸

Dr. Frank D. Lazzerini of Summit County ran a "pill mill" out of his office, and had his license suspended in June 2016 for over-prescribing pain medication.⁹

⁸ <https://www.ohio.com/news/20181123/chinese-chemist-who-supplied-drugs-that-left-two-dead-in-summit-county-heading-to-prison>; see also <https://www.ohio.com/akron/news/akron-man-sentenced-to-life-in-prison-for-overdose-death-of-akron-woman-ordered-to-pay-her-funeral-expenses>.

⁹ <https://www.ohio.com/akron/writers/betty-linfisher/jackson-twp-doctor-indicted-on-272-counts-including-involuntary-manslaughter-for-allegedly-operating-a-pill-mill>.

Dr. Michael P. Tricaso, founder of the Better Living Clinic and a former contracted emergency room physician with Summa Health, was permanently barred from prescribing opioids in October 2018 after he was found to have been illegally prescribing opioids.

Rafael Jones was sentenced to 12 years in prison late last year for illegally selling fentanyl, a fatal dose of which killed a Brunswick man in 2017.¹⁰

Manufacturers have also targeted the following most prolific prescribers in Summit County:

Dr. Syed Ali	
Dr. Guang Yang	Actavis identifies him as one of "the two largest Morphine Sulfate prescribers in Ohio." (ACTAVIS0339963) He is also identified as a high Kadian prescriber. (ACTAVIS0666775)
Dr. Michael Wells	
Dr. Mathew Taylor	Purdue contacted him forty-four times. (PPLPMDL0080000001, PPLPMDL0020000001)
Dr. Clayton Seiple	Purdue lists Seiple as a target. (PPLP004367799, PPLP004367801, PPLP004367820)
Dr. Dmitri Souzadalnitski	
Dr. Kendrick Bashor	<p>Endo lists Bashor as a target. (ENDO-CHI LIT-0017676, ENDO-CHI LIT-0184289, ENDO-CHI LIT-0253540, ENDO-CHI LIT-0253901, ENDO-CHI LIT-0255569, ENDO-CHI LIT-0025528, ENDO-OPIOID_MDL03203444, ENDO-OPIOID_MDL03479738, ENDO-OPIOID_MDL0282893, ENDO-OPIOID_MDL02819109, ENDO-OPIOID_MDL02859740, ENDO-OPIOID_MDL02859745)</p> <p>Mallinckrodt lists Bashor as a priority for Exaglo and Pennsaid (MNK-T1_0000106614, MNK-T1_0000106646, MNK-T1_0000106656, MNK-T1_0000106660, MNK-T1_0000107152)</p> <p>Mallinckrodt lists Bashor as a high opioid prescriber. (MNK-T1_0002159629, MNK-T1_0002211431)</p> <p>Purdue lists Bashor as number one program to date of rankings of prescribers for OxyContin. (PPLPC012000498497, PPLPC012000511300)</p>

¹⁰ <https://www.ohio.com/news/20181026/federal-judge-bars-akron-doctor-from-prescribing-opioids>.

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	<p>Teva lists Bashor as a Fentora target doctor. (TEVA_MDL_A_00677052)</p> <p>Janssen lists Bashor on a target list. (JAN-MS-02403471, JAN-MS-02404040, JAN-MS-02404790)</p>
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Others identified as engaging in inappropriate prescribing or other illegal acts concerning diversion of Opioids in Summit County identified to date include:

Dr. Ronald Celeste
Dr. Gregory Gerber
Dr. Gregory Ingram
Louis Eppinger
Patricia Arnold
Anthony H. Perry
Elizabeth Davis
James Byrge
Judy Barrows
Brittany Glass

Plaintiff identifies the following investigations into pill mills, pharmacies and opioid diversion within its boundaries:

Bates	Date	Summary
SUMMIT_000038070	7/22/2011	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of "Initiative Activities," indicates one (1) pharmaceutical case involving a pharmacy
SUMMIT_000072338	4/28/2014	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of "Initiative Activities," indicates one (1) pharmaceutical case involving a doctor and one (1) pharmaceutical case involving a pharmacy
SUMMIT_000074754	3/13/2017	2016 Ohio Multi-Jurisdictional Task Force Report-- gives stats on pharmaceutical/pharmacy/and individual pharmacy employee investigations
SUMMIT_001000530	7/18/2014	Summit HIDTA Quarterly DTO/LMO Report: Activities Report, under heading of "Initiative Activities," indicates one (1) pharmaceutical case involving a doctor and one (1) pharmaceutical case involving a pharmacy

Bates	Date	Summary
SUMMIT_001002135	11/20/2008	11/2008 DB Intel Meeting @ SUMMIT_001002136 report of burglary at Ritzman Pharmacy; large amount of Oxycontin stolen
SUMMIT_001006223	10/7/2016	January – June: 2016 Ohio Multi-Jurisdictional Task Force Report—gives stats on pharmaceutical/pharmacy/and individual pharmacy employee investigations
SUMMIT_001006365	12/2/2016	Drug Interdiction, Disruption and Reduction Plan for the Ohio Department of Public Safety “... OCJS-funded task forces participated in pharmaceutical diversion investigations in 2014. Task forces initiated 1,261 pharmaceutical diversion investigations and indicted 716 individuals, 90 of whom were health care professionals.” Examines Ohio overall @ SUMMIT_001006374
SUMMIT_001007719	6/8/2016	Email from Lori Baker-Stella to Paolino; she mentions she has several complaints from the Ohio Pharmacy Board that she has opened and begun working
SUMMIT_001129537	4/30/2015	Email from Daniel Lance to many individuals forwarding an email from Barberton Detective Robert Russell re: a robbery of Rite Aid Pharmacy in which suspect took “a few bottles of Hydrocodone.”
SUMMIT_001132080	3/17/2015	Akron/Summit Case Chart including Total number of Pharmaceutical Cases involving a doctor and cases involving a pharmacy in 2014; also broken down by Akron, and Summit individually.
AKRON_000321799	8/10/2017	Daily report for 8/10/2017 for Akron Police Department; includes report of CVS pharmacy being robbed of narcotics and pain medications
AKRON_000322914	9/25/2017	Daily report for 9/25/2017 for Akron Police Department; includes report of CVS pharmacy being robbed of various medications; does not mention opioids but does contain a report number that could possibly be cross-referenced
AKRON_000325028	7/18/2017	Daily report for 7/18/2017 for Akron Police Department; includes report of CVS pharmacy being robbed of miscellaneous pain medications
AKRON_000330904	5/10/2012	Report on Walgreen’s being robbed of Percocet and Ambian

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Bates	Date	Summary
AKRON_000334652	2/17/2015	Report of CVS Pharmacy robbed for Oxymorphone at gunpoint
SUMMIT_001233883	11/20/2008	Report of pharmacy being robbed of a large amount of Oxycontin
AKRON_000335652	2/16/2015	Report of CVS Pharmacy attempted robbery of Oxymorphone
AKRON_000337173, AKRON_000337174	3/1/2016	Email and media release from Summit County's prosecutor's office reporting the sentencing of Alexander Linton for robbing several pharmacies of Oxycodone/Oxymorphone at gunpoint
AKRON_000338005	9/23/2015	Report of CVS Pharmacy attempted robbery of Oxymorphone by Alexander Linton
AKRON_000338159	5/9/2016	Akron Police Incident Report re: Christopher Richard, pharmacy technician at AGMC; alleged to have stolen a syringe of Fentanyl for personal use
SUMMIT_001444634	9/16/2013	Email from Pat Hunt to Lori Baker-Stella responding to Baker-Stella's email relaying some data entry she is doing "for our Pharmacy case."
AKRON_000366415, AKRON_000366435	9/23/2017	Emails from Walgreens to Summa Barberton and from Gregory Smith to Walgreens with Patrick Leonard copied re: Summa Barberton ERs OARRS practices. This email was in response to issues Walgreens noted with Summa Barberton ERs prescriptions
AKRON_000368006	10/28/2009	Email from Tom Miksch (agent with the Board of Pharmacy) to Patrick Leonard re: Walgreen B&E; 8000 to 9000 Percocet and Oxycontin stolen
AKRON_000368458, AKRON_000368459	1/14/2013	Email from Tom Miksch to Patrick Leonard and others re: Pearl Lantz interview with attached Ohio State Board of Pharmacy Report of Investigation on Adolph Harper, MD for his pain management practice
AKRON_000368462, AKRON_000368463	12/23/2012	Email from Tom Miksch to Patrick Leonard and others re: Interview of Harper patient Sarah Weiss with attached Ohio State Board of Pharmacy Report of Investigation on Adolph Harper, MD for his pain management practice
AKRON_000368700	1/27/2014	Email thread including email from Tom Miksch to Patrick Leonard re: completed case of pharm tech stealing drugs from Walgreens
AKRON_000369026	12/11/2012	Email from Tom Miksch to Cathy Hanselman and others including Patrick Leonard re: Summit County

Bates	Date	Summary
		Coroner Reports; also attaches a death report of a Harper patient who died of a heroin/alcohol combo
AKRON_000369048	1/21/2013	Email from Tom Miksch to Patrick Leonard and others re: Kelly Pamer Autopsy Report from Medina County; also attaches a death report of a Harper patient who died of a alpraxolam/oxycodone combo
AKRON_000369105	1/10/2014	Medina County Drug Task Force Pharmacy Alert – Statewide: Compromised DEA Numbers to obtain Codeine w/Promethazine. Physician office located in Wadsworth, Akron, and Canton
AKRON_000369430, AKRON_000369431	11/28/2014	Email and attached Fax sheet from Agent Thomas Miksch to Pharmacist re: Hotline Information about an unarmed pharmacy robbery in Stow; suspect asked specifically for oxymorphone and oxycodone
AKRON_000369539, AKRON_000369555	3/27/2015	Emails from Hugh Schuckman to Patrick Leonard re: Robert Wiseman lying to pharmacy about 90 hydrocodone script being stolen
AKRON_000369671, AKRON_000369672	8/6/2015	Email from Helene Hall (Ritzman Pharmacy) to Patrick Leonard re: an individual selling percocets and having prescriptions filled at the pharmacy
AKRON_000369680	7/31/2015	Heavily redacted U.S. DOJ DEA report re: RX Fraud/Forgery at Walgreen's.
AKRON_000370688	10/1/2015 – 12/31/2015	National Diversion Survey Questionnaire; lists number of cases involving particular drugs including opioid during the reporting period
SUMMIT_001461044	8/10/2005	2005 Ohio Office of Criminal Justice Services Byrne Memorial Grant Program; Area A: Law Enforcement Task Forces Semi-Annual Performance Report for the Summit County Drug Unit; stats for health professional involved in pharmaceutical diversion and dosages of drugs seized which include opioids
SUMMIT_001461060 SUMMIT_001461068	7/19/2006	2006 Ohio Office of Criminal Justice Services Byrne Memorial Grant Program; Area A: Law Enforcement Task Forces Semi-Annual Performance Report for the Summit County Drug Unit; stats for health professional involved in pharmaceutical diversion and dosages of drugs seized which include opioids

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Bates	Date	Summary
AKRON_001127725	8/24/2016	Akron police department report/Zone Report on individual robbed of Oxycontin after leaving the pharmacy
AKRON_001129036	8/10/2017	Akron Police Department report/Zone Report, Allen Shayne Oded and admitted using three doses of Percocet along with heroin; another report the robbery of a CVS for Oxycontin
AKRON_001131778	9/5/2017	Akron Police Department report/Zone Report, Rite Aid pharmacy robbed of Oxycodone, percocet, and codeine
AKRON_001137270	7/1/2016	Akron Police Department report/Zone Report, unknown suspect, possibly drunk, threatened to "shoot up" CVS and asked for Percocets.
AKRON_001138256	8/9/2012	Northeast Ohio Regional Fusion Center Crime/Intel Bulletin; FBI Cleveland Division cites pattern of Walgreen pharmacy robberies across several states, including in Ohio, in which Oxycontin, Percocet, and other controlled substances are stolen
AKRON_001139534	2/23/2015	Daily Report of Major Incident includes report of Andrew P. Norris, charged with Deception to obtain and Illegal Processing of Drug Documents after he presented an altered prescription for Oxycodone to a pharmacy
AKRON_001139901	9/23/2015	Daily Report of Major Incident includes report of Alexander Linton who was charged with aggravated robbery of a CVS pharmacy after approaching the pharmacist with a handgun and demanding Oxymorphone.
AKRON_001150411	4/10/2017	Akron Police Department All Zones Reports; includes report of Ashley Evans who robbed her friend of 10 Percocet; also report of CVS Pharmacy robbery by an unknown suspect who took Hydrocodone
AKRON_001151693	8/2/2011	Request for Service/Information Report: photo of suspect who stole 300 doses of Percocet from an Akron Walgreens.
AKRON_001153252	7/1/2014	Akron Police Department Zone Reports; includes report of medical office manager for Dr. Sheela Rao stating someone stole blank prescription forms and the office was notified by Giant Eagle pharmacy of an individual attempting to refill a prescription that contained codeine for a third time

Bates	Date	Summary
AKRON_001160846	10/22/2014	Report of Derrick L. Watley attempting to get Opana with a fake prescription at a CVS pharmacy
AKRON_001175294	6/2/2010	CAD Email with information on Amy Baird (Akron), a Pharmacy Tech who, in the past year, stole approximately \$11,074.64 of Hydrocodone from CVS.
AKRON_001208468	6/23/2009	CAD Email re: Report of Vince R. Johnson, Jr. attempting to receive unprescribed Xanax and Vicodin from pharmacy
AKRON_001210410	4/30/2015	Email re: robbery of Rite Aid Pharmacy in Barberton. Suspect took a few bottles of Hydrocodone
AKRON_001242846, AKRON_001242849, AKRON_001242852	2/16/2010	Emails from Robert Lehman to Erika Wells re: B&E at Highland Square Pharmacy; primary drug taken was Hydrocodone
AKRON_001243531	10/29/2010	Northeast Ohio Regional Fusion Center Weekly Crime/Intel Bulletin Contains report of Stow Police Department responding to a report of a CVS pharmacy robbery in which the suspect demanded the store's supply of 40mg Opana (@ AKRON_001243532)
AKRON_001247738	2/11/2010	Akron Police Department, Zone 1 Incidents: Report of B&E of Highland Square Pharmacy on 2/11/2010; Hydrocodone and Hydromorphone taken
AKRON_001247754	2/17/2010	Akron Police Department, Zone 1 Incidents: B&E at Highland Square Pharmacy; hydrocodone taken on 2/16/10
AKRON_001247770, AKRON_001247771	3/24/2010	Email and attached flyer re: two individuals, Philip Whited who met officers to sell Oxycodone and was found with pills on his person, and Troy Edgehouse, suspected in connection with Highland Square Pharmacy B&E
AKRON_001252089	10/23/2014	Email about fraudulent prescription orders for Phenergan with Codeine called into a CVS pharmacy in Copley, Ohio on several occasions using three different doctors' names and DEA tracking numbers
AKRON_001818328	4/9/2012	Email from Norton Police Dept. with Patrick Leonard copied re: Report from CVS Pharmacy about Robyn Swenson calling in a Norco order for Jason Baylor by Dr. Adolph who says he did not order the script.
AKRON_001312626, AKRON_001312627,	2/17/2010	Email from Tom Miksch to Patrick Leonard re: Doctor Shopper, Thomas Eckel with attached Ohio State Board

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Bates	Date	Summary
AKRON_001312629		of Pharmacy report showing his multiple prescriptions for various prescription opioids, drug report
AKRON_001312637	11/5/2010	Email from Hugh Schuckman to Patrick Leonard re: Joseph Michael, patient with 44 scripts from 16 providers with 8 pharmacies. Doctor/script shopping.
SUMMIT_000074835 SUMMIT_001444018	4/5/17	Email- update on cases. "case with KNR is still being worked. There is currently a civil suit against KNR in the Summit County Courts. We are in contact with an Attorney out of Columbus with info from a current doctor working at office. FBI is also involved in this case. Working case looking to take that to grand jury shortly. Just opened a new case on it's a mental health Suboxone clinic. They have 5 locations. Main doctor is Dr. Ranjan."

Finally, hundreds of depositions of fact witnesses have been taken of defense witnesses and bellwether Plaintiffs utilizing hundreds of exhibits. The discovery performed to date, including depositions and document productions, provides details of statements and omissions made or disseminated that were false, misleading, unfair and deceptive. It is not practicable to specifically identify each and every instance of opioid diversion or every responsive document. Plaintiffs reserve the right to rely upon and introduce as evidence any and all deposition testimony and exhibits addressing this topic.

Plaintiff reserves the right to supplement or amend its response as expert discovery commences, and this issue may be the subject of fully-supported and detailed expert witness opinion(s).

Interrogatory No. 21

For each opioid-containing product of each Manufacturer Defendant that you maintain or allege is at issue in this case, describe any risk that Plaintiff alleges is not adequately disclosed in such opioid-containing product's operative FDA-approved prescribing information. For each opioid-containing product for which you cannot identify any such risks, please so state. For each

opioid-containing product for which you maintain or allege there are such inadequately disclosed risks, please include in your description (i) the risk; (ii) the medical or scientific support for your assertion, if any; (iii) any communications between Plaintiff or anyone acting on Plaintiff's behalf and the Manufacturer Defendant in which Plaintiff or anyone acting on Plaintiff's behalf alerted, discussed or disclosed such risk to the manufacturer Defendant or other third party prior to filing this litigation; and (iv) any communications between Plaintiff or anyone acting on Plaintiff's behalf and the FDA in which Plaintiff or anyone acting on Plaintiff's behalf alerted, discussed or disclosed such risk to the FDA prior to filing this litigation.

Response:

Plaintiff repeats and reasserts its prior objections and adopts its prior responses to this Interrogatory. Plaintiff objects to this Interrogatory as vague, ambiguous in seeking "FDA-approved prescribing information." Plaintiff objects to this Interrogatory as vague, overly broad and unduly burdensome to the extent it requests "any communications." Plaintiff further objects to this Interrogatory in that it seeks information already in the possession of the Manufacturer Defendants and third parties, and thus seeks to impose an undue burden and unnecessary expense on Plaintiff. Plaintiff objects to this Interrogatory to the extent it calls for an expert opinion. Plaintiff objects to this request as an improper contention interrogatory.

Subject to and without waiver of all objections, Plaintiff responds as follows: Plaintiff does not contend that the labels of Defendants' Opioid products were misleading or inadequate at the time they were first approved, but that Defendants' marketing was misleading to the extent that it contradicted, undermined, or exceeded their labels. Over time, however, as the magnitude of the opioid epidemic became apparent, the labels of Defendants' Opioid products became inadequate

or misleading to the extent they did not address or correct widespread misunderstandings, many deliberately seeded by Defendants that were contributing to the epidemic.

Plaintiff further notes that *Wyeth v. Levine*, 129 S. Ct. 1187, 1197-98 (2009), makes clear that drug companies are responsible for ensuring that their drug labels completely and accurately communicate the risks and benefits of their products.

Further, because this topic only seeks disclosure of “risks” that the relevant opioid labels did not disclose, Plaintiff reserves the right to contend that Defendants should have sought to make changes to their labels to better describe the appropriate indications, use, and administration of their drugs.

Post-launch labels for all branded Opioid products sold or distributed by the Defendants should have communicated at least the following risks earlier in time than they were disclosed to the extent they ever were disclosed. The items that were never disclosed should have been added to the post-launch labels at the point when the Defendants learned of the widespread misunderstandings regarding the opioid epidemic.

- Higher doses of opioids increase risks of addiction, dependence, tolerance, other side-effects and death.
- Use of opioids, even when taken as recommended, can result in addiction, abuse, and misuse, which can lead to overdose or death.
- There is risk of opioid addiction and abuse even in those without prior history of addiction, abuse, or mental health issues.
- To the extent that an Opioid product used abuse-deterrent labeling, abuse-deterrent formulations provide no protection against addiction if taken as prescribed or as formulated.
- The use of Opioid products, particularly at high doses, may compromise patients’ functionality and quality of life.
- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve [opioid drug] for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids)

are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

- High risk populations such as those with substance abuse or mental health problems because they are at higher risk of addiction should be closely monitored.
- Opioid product contains a narcotic pain medicine that can be a target for people who abuse prescription medicines. Keep your Opioid product in a safe place, to protect it from theft. Never give Opioid product to anyone else because it may be dangerous to them. Selling or giving away this medicine is against the law.
- Prolonged use of Opioid products during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.
- Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.

Reserve concomitant prescribing of opioids and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.

- Serious, life-threatening, or fatal respiratory depression may occur with use of Opioid products. Monitor for respiratory depression, especially during initiation of Opioid product or following a dose increase. Instruct patients to swallow Opioid product tablets whole; crushing, chewing, or dissolving Opioid product tablets can cause rapid release and absorption of a potentially fatal dose of opioids.

Plaintiff specifically disavows any intention of asserting that Defendants should have made any disclosures that were considered and rejected by the Food and Drug Administration.

Plaintiff continues to receive and review documents from Defendants and third parties, and reserves the right to supplement or amend this answer as that review continues. In addition, Plaintiff may serve expert disclosures on or before the applicable deadline concerning the issues in this interrogatory.

Interrogatory No. 26

Identify all entities and individuals besides the Defendants named in Plaintiff's Second Amended Corrected Complaint who Plaintiff contends caused or contributed in any way to the

alleged “public nuisance” or “health crisis” (as those terms are used in Plaintiff’s Second Amended Corrected Complaint, including in paragraph 171). Include in your identification for each entity or individual: (i) their role in helping to cause or contributing in any way to the “public nuisance” or “health crisis” (as those terms are used in Plaintiff’s Second Amended Corrected Complaint, including in paragraph 171); and (ii) the specific actions or efforts, if any, Plaintiff has undertaken to mitigate the effects of those third parties’ actions or omissions.

Response:

Plaintiff repeats and reasserts its prior objections and adopts its prior responses to this Interrogatory. Plaintiff objects to this Interrogatory as vague, overly broad and unduly burdensome to the extent it requests “all” entities and individuals besides the Defendants named in Plaintiff’s Second Amended Corrected Complaint who Plaintiff contends caused or contributed in any way to the alleged “public nuisance” or “health crisis” (as those terms are used in Plaintiff’s Second Amended Corrected Complaint, including in paragraph 171). Plaintiff does not and would not necessarily know the identities of entities and individuals who may have caused or contributed to the “public nuisance” or “health crisis.” Plaintiff also objects to this Interrogatory to the extent it calls for an expert opinion. Plaintiff further objects that this Interrogatory is contention discovery more appropriately answered once discovery is complete. *See* FRCP 33(a)(2).

It is not practicable to specifically identify each and every entity and individual herein. Plaintiff reserves the right to rely upon and introduce as evidence any and all deposition testimony and exhibits addressing this topic. Also, Plaintiff’s discovery, document review and investigation are continuing, and Plaintiff reserves their right to rely upon and introduce further evidence addressing this topic. For purposes of illustration, including by way of examples, Plaintiff supplements its responses as follows:

In addition to the Defendants, all of whom Plaintiff contends caused to the public nuisance and health crisis described in Plaintiff's Second Amended Corrected Complaint, other entities, working groups, trade associations, and key opinion leaders, including but not limited to the following, contributed to the public nuisance and health crisis described in Plaintiff's Second Amended Corrected Complaint:

- **American Pain Foundation.** Among other things, The American Pain Foundation published *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use. In addition, the American Pain Foundation published *Treatment Options: A Guide for People Living with Pain* (2007), which suggests that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative prescriptions, or theft.
- **American Academy of Pain Medicine.** Among other things, the American Academy of Pain Medicine, with the American Pain Society, issued a "consensus" statement in 1997 that endorsed opioids to the treat chronic pain and claimed that the risk patients would become addicted to opioids was low. *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 Clinical J. Pain 6 (1997). In addition, the American Academy of Pain Medicine and the American Pain Society issued guidelines in 2009 that continued to recommend the use of opioids to treat chronic pain. See Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).
- **American Pain Society.** Among other things, the American Pain Society, with the American Academy of Pain Medicine, issued a "consensus" statement in 1997 that endorsed opioids to the treat chronic pain and claimed that the risk patients would become addiction to opioids was low. *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 Clinical J. Pain 6 (1997). In addition, the American Academy of Pain Medicine and the American Pain Society issued guidelines in 2009 that continued to recommend the use of opioids to treat chronic pain. See Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).
- **Federation of State Medical Boards.** Among other things, the Federation of State Medical Boards published *Responsible Opioid Prescribing* in 2007, written by Dr. Scott Fishman, which taught that behaviors such as "requesting drugs by name," "demanding or

manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, which are signs of genuine addiction, are all really signs of “pseudoaddiction.”

- **Alliance for Patient Access.** Among other things, the Alliance for Patient Access’ board members directly received substantial funding from pharmaceutical companies in return for supporting Defendants’ activities. For instance, board vice president Dr. Srinivas Nalamachu, who practices in Kansas, received more than \$800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids’ side effects, including from Purdue. Other board members include Dr. Howard Hoffberg from Maryland, who received \$153,000 between 2013 and 2015 from pharmaceutical companies, including Purdue; and Dr. Robin K. Dore from California, who received \$700,000 between 2013 and 2015 from pharmaceutical companies, including Purdue.
- **U.S. Pain Foundation.** Among other things, the U.S. Pain Foundation was a component of Purdue’s lobbying efforts to reduce the limits on over-prescription.
- **American Geriatrics Society.** Among other things, the American Geriatric Society contracted with Purdue, Endo and Janssen to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*) and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*). *Pharmacological Management of Persistent Pain in Older Persons* stated that “[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy.”
- **Dr. David Haddox.** Among other things, Dr. Haddox authored a 1989 article that advanced the concept of pseudoaddiction.
- **Dr. Russell Portenoy.** Among other things, Dr. Portenoy, who was paid by Purdue and other Defendants as a key opinion leader to minimize the risk of opioids, co-wrote (with Dr. Perry Fine) *A Clinical Guide to Opioid Analgesia*, which downplayed the risks of opioid treatment. Dr. Portenoy admitted that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.” Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, *The Wall St. J.*, <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.
- **Dr. Lynn Webster.** Among other things, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. Dr. Webster gave a 2011 webinar sponsored by Purdue, entitled *Managing Patient’s Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing “overuse of prescriptions” and “overdose deaths.” In addition, in a 2007 book, Dr. Webster wrote that when faced with signs of aberrant behavior, increasing the dose “in most cases . . . should be the clinician’s first response.” Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007). Dr. Webster subsequently admitted that pseudoaddiction “is already something we are

debunking as a concept” and became “too much of an excuse to give patients more medication. It led us down a path that caused harm.”

- **Dr. Perry Fine.** Among other things, Dr. Perry co-wrote (with Dr. Portenoy) *A Clinical Guide to Opioid Analgesia*, which downplayed the risks of opioid treatment.
- **Dr. Scott Fishman.** Among other things, Dr. Fishman stated that he would place the American Academy of Pain Medicine “at the forefront” of teaching that “the risks of addiction are . . . small and can be managed.” <http://www.medscape.org/viewarticle/500829>. In 2007, Dr. Fishman authored a physician’s guide on the use of opioids to treat chronic pain titled *Responsible Opioid Prescribing*, which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain. In 2012, Dr. Fishman updated the guide and continued emphasizing the “catastrophic” “under-treatment” of pain and the “crisis” such under-treatment created. Scott M. Fishman, *Responsible Opioid Prescribing: A Guide for Michigan Clinicians*, 10-11 (Waterford Life Sciences, 2d ed. 2012). The updated guide assures that “[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and noncancer origins.” *Id.*
- **Pain Care Forum.** Among other things, the Pain Care Forum facilitated the flow of information and influenced state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution.
- **Healthcare Distribution Alliance.** Among other things, Healthcare Distribution Alliance, formerly known as the Healthcare Distribution Management Association, facilitated meetings designed to exchange detailed information regarding prescription opioid sales and to control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution.
- **Open Society Institute.** Among other things, Open Society Institute contributed millions of dollars to Fleishman-Hillard, a public relations and marketing agency, and the University of Wisconsin-Madison School of Medicine and Public Health to create false information on the dangers of opioids, as well as to influence state and federal policy makers for the purpose of benefitting pharmaceutical corporations.
- **Robert Wood Johnson Foundation.** Among other things, Robert Wood Johnson Foundation contributed millions of dollars to Fleishman-Hillard, a public relations and marketing agency, and the University of Wisconsin-Madison School of Medicine and Public Health to create false information on the dangers of opioids, as well as to influence state and federal policy makers for the purpose of benefitting pharmaceutical corporations.

In addition, Plaintiff identifies the following entities contributing to the public nuisance and health crisis described in Plaintiff’s Second Amended Corrected Complaint:

- Pain Care Forum
- Anti-Diversion Industry Working Group (“ADIWG”)
- New Jersey Pharmaceutical Working Group (“NJPIG”)
- Midwestern Discussion Group (“MWDG”)
- Pharmaceutical Research and Manufacturers of America (“PhRMA”)
- Generic Pharmaceutical Association (now re-branded as the Association of Accessible Medicines) (“GPhA”)
- Biotechnology Innovation Organization (“BIO”)
- National Association of Chain Drug Stores (“NACDS”)
- The Joint Commission
- American Chronic Pain Association
- Center for Practical Bioethics
- Pain and Policy Studies Group
- Ohio Pain Initiative
- American Pain Association
- Ohio Pain Initiative (“OPT”)
- American Pain Foundation (“APF”)
- American Academy of Pain Medicine (“AAPM”)
- Federation of State Medical Boards (“FSMB”)
- Joint Commission (“JACHO”)
- American Pain Society (“APS”)
- American Society of Pain Educators (“ASPF”)
- The Alliance for Patient Access (“APA”)
- The U.S. Pain Foundation (“USPF”)
- American Geriatrics Society (“AGS”)
- Healthcare Distribution Alliance

Plaintiff further directs Defendants to the following list of doctors and healthcare providers as having helped to contribute to the public nuisance or health crisis:

Name	Title	Event Description
Steven Simon	Doctor at Mid-America Psychiatrists in Overland Park, Kansas	Wrote prescriptions for Subsys and Fentanyl and was a designated paid “speaker” for Insys
Robert Yapundich	Neurologist in Hickory, North Carolina	Board member of the Alliance for Patient Access and paid “speaker”

Howard Hoffberg	Doctor at Rosen-Hoffberg Rehabilitation and Pain Management Associates in Townson, Maryland	Wrote prescriptions for opioids and received “speaker” fees from Insys, Purdue and Teva
Heather Alfonso	Nurse practitioner in Connecticut	Wrote prescriptions for Subsys in exchange for “speaker” fees from Insys.
Jerrold Rosenberg	Doctor in Rhode Island	Wrote prescriptions for Subsys in exchange for “speaker” fees from Insys
Gordon Freedman	Doctor in New York, New York	Wrote prescriptions for Fentanyl in exchange for “speaker” fees from Insys
Jeffrey Goldstein	Doctor in New Rochelle, New York	Wrote prescriptions for Fentanyl in exchange for “speaker” fees from Insys
Todd Schlifstein	Doctor in New York, New York	Wrote prescriptions for Fentanyl in exchange for “speaker” fees from Insys
Dialecti Voudouris	Doctor in New York, New York	Wrote prescriptions for Fentanyl in exchange for “speaker” fees from Insys
Alexandru Burducea	Doctor in Little Neck, New York	Wrote prescriptions for Fentanyl in exchange for “speaker” fees from Insys
Michael Frey	Doctor in Florida	Wrote prescriptions for Subsys in exchange for “speaker” fees from Insys
Jeffrey Kesten	Doctor in Boulder, Colorado	Wrote prescriptions for Subsys in exchange for “speaker” fees from Insys
Gordon Freedman	Doctor in White Plains, New York	Wrote prescriptions for Subsys in exchange for “speaker” fees from Insys

Plaintiff directs Defendants to its response to Manufacturer Interrogatory No. 29. Plaintiff also identifies the following as contributing to:

- Trade Associations and Front Groups

- Pill Mills (*see* Plaintiff's response to Manufacturer Interrogatory No. 20)
- Drug Cartels
- PBMS
- Insurers
- Independent Pharmacies

Plaintiff reserves the right to supplement or amend its response as expert discovery commences, and this issue may be the subject of fully-supported and detailed expert witness opinion(s).

Interrogatory No. 27

For each Manufacturer Defendant, identify and describe each "suspicious order[]" of opioids that each Manufacturer Defendant was under a "duty to report" and "not ship" (as those terms are used in Plaintiff's Second Amended Corrected Complaint, including in paragraph 501). For each such identification and description, include (i) the date(s); (ii) the opioid-containing product or products involved; (iii) the destination of the shipment; (iv) whether the manufacturer reported or shipped the order; and (v) Plaintiff's basis for its contention that such shipment should have been "report[ed]" and not ship[ped]" (as those terms are used in Plaintiff's Second Amended Corrected Complaint, including in paragraph 501). For each Manufacturer Defendant for which Plaintiff can identify no such order, please so state.

Response:

Plaintiff repeats and reasserts its prior objections and adopts its prior responses to this Interrogatory. Plaintiff reserves the right to supplement this answer through expert witnesses pursuant to the Scheduling Order entered by the Court. Plaintiff intends to disclose through expert testimony: (a) orders previously designated by each distributor as suspicious; (b) orders which should have been designated as suspicious using the system designed and operated by each

distributor; and (c) orders which should have been designated as suspicious using a “common sense” approach.

Plaintiff incorporates by reference its “Responses to the Amended and Clarified Discovery Ruling 12 Supplemental Interrogatory Issued to Plaintiffs” dated January 25, 2019 (Pharmacy Interrogatory No. 7 and Distributor Interrogatory No. 23); “Responses to Supplemental Interrogatory Issued in Discovery Ruling 12 to Plaintiffs” dated January 11, 2019 (Pharmacy Interrogatory No. 7 and Distributor Interrogatory No. 23); “Supplemental Amended Responses and Objections to the Manufacturer Defendants’ First Set of Interrogatories, Submitted Pursuant to Discover Ruling No. 13” dated December 31, 2018 (Manufacturer Interrogatory No. 6); “Supplemental Objections and Responses to Manufacturer Defendants’ Interrogatory Nos. 27/28” dated December 21, 2018; “Fourth Amended Responses and Objections to Manufacturer Defendants’ First Set of Interrogatories” dated December 14, 2018 (Manufacturer Interrogatory Nos. 6 & 10); “Supplemental Responses & Objections to Reformulated Suspicious Order Interrogatory Served by Manufacturer Defendants” dated November 27, 2018 (Manufacturer Interrogatory No. 27); “Amended Responses and Objections to the Manufacturer Defendants’ First Set of Interrogatories and the National Retail Pharmacy Defendants’ First Set of Interrogatories” dated November 2, 2018 (Manufacturer Interrogatory No. 10 and Pharmacy Interrogatory Nos. 2 & 3); “Amended Responses and Objections to the National Retail Pharmacy Defendants First Set of Interrogatories and Distributor Defendants’ Fourth Set of Interrogatories” dated October 31, 2018 (Distributor Interrogatory No. 23 and Pharmacy Interrogatory No. 7); “Responses and Objections to Distributor Defendants’ Fourth Set of Interrogatories” dated August 31, 2018 (Distributor Interrogatory Nos. 23 & 29); “First Amended Responses and Objections to Distributor Defendants’ Third Set of Interrogatories” dated August 13, 2018 (Distributor Interrogatory Nos.

16 & 17); and “Initial Responses and Objections to Manufacturer Defendants’ Second Set of Interrogatories” dated July 5, 2018 (Manufacturer Interrogatory No. 27).

In addition, Plaintiff responds as follows:

This discovery request is a contention interrogatory. “Contention” interrogatories seek to clarify the basis for or scope of an adversary’s legal claims. *Starcher v. Corr. Med. Sys., Inc.*, 144 F.3d 418, fn. 2 (6th Cir. 1998), *aff’d sub nom. Cunningham v. Hamilton Cty., Ohio*, 527 U.S. 198, 119 S. Ct. 1915, 144 L. Ed. 2d 184 (1999).

To be clear, it is the position of the Plaintiff answering herein, that the answer to this contention interrogatory “does not limit [our] experts from using different criteria to identify suspicious orders, and therefore from concluding that there exist suspicious orders in addition to those identified [herein].” Discovery Ruling No. 7, p. 6.

Plaintiff objects to this Interrogatory to the extent that it seeks identification of suspicious orders shipped to pharmacies outside of their geographic answer. Discovery in the current phase of the MDL has been largely limited to the jurisdictions comprising the Track One cases and, in connection with the analogous Interrogatory posed by Distributor and Pharmacy Defendants, Special Master Cohen reformulated the Interrogatory to seek only identification of suspicious orders “shipped to Your geographic area.” *See, e.g.*, Discovery Ruling No. 7, Dkt. 1051 at 5. Plaintiff contends that the same limitation should apply to the current interrogatory.

Plaintiff further objects to this Interrogatory to the extent that responsive information is at least as available to Defendants as to Plaintiff. Indeed, information necessary to respond fully to this Interrogatory is more readily available to Defendants. Specifically, discovery to date has revealed that such information is readily available to Defendants from one or more of the following sources: chargeback data provided to Manufacturers by Distributors, data provided by Distributors pursuant to Fee For Service (FFS) Agreements with Manufacturers, EDI data, 867 data, and/or

sophisticated prescriber/patient-level data Manufacturers obtained from data vendors like IMS as part of their sales/marketing strategies. Thus, Defendants had and currently have it within their ability to identify all transactions from the produced list that involve their own opioid products. Nevertheless, Plaintiff will provide Defendants with sufficient information about the methodology by which it has identified suspicious orders to permit Defendants to duplicate the analysis with their own particular orders.

Although Defendants have objected to Plaintiff's prior responses to this Interrogatory as listing only transactions between distributors and pharmacies, Plaintiff contends that those are suspicious orders as to which Defendants had duties to report and to (attempt to) stop shipment. The duty under federal law to report suspicious orders is not limited to orders actually shipped by the Manufacturer. Indeed, upon recommending the denial of Manufacturer Defendants' Motion to Dismiss, the Court held that the text of 21 U.S.C. § 823 and 21 C.F.R. § 1301.74 are not so limiting as to exempt the Manufacturer Defendants from the requirement to identify and report orders beyond their direct customers – i.e. downstream orders. *See* Report & Recommendation, Dkt. 1025, at 74. Moreover, discovery has revealed that most distributor agreements between Manufacturers and Distributors expressly define the retail level customers (pharmacies) that receive shipments from the Distributor Defendants as "customers" of the Manufacturer, not the Distributor. They are therefore suspicious orders attributable to the Manufacturer of that product. Furthermore, although the Manufacturer Defendants have taken the position that they were not in a position to halt orders between Distributors and customers, discovery to date has revealed that Manufacturers were able (and sometimes threatened) to use their refusal to process chargebacks for sales between Distributors and customers identified as having placed suspicious orders to effectively terminate the processing of suspicious orders, and Plaintiff reserves its right to identify additional orders based on this information. Finally, although Manufacturers have taken the

position that they could not halt orders between Distributors and customers, this position ignores the ability of Manufacturers to halt orders from Distributors whom they knew were filling suspicious orders by customers, all of which could have been deemed suspicious and for which Plaintiff reserves its right to identify additional orders based on this information.

Plaintiff contends each Manufacturer and Distributor Defendant, as a registrant, owes a duty under federal law and implementing regulations to maintain “effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, and industrial channels.” 21 U.S.C.A. § 823(a)(1). This duty, which is identical to the duty applied to distributors pursuant to 21 U.S.C.A. § 823(b)(1), has been defined to include certain “security requirements” identified in 21 C.F.R. § 1301.72-1307.76 which the DEA has imposed on all registrants and deemed “necessary to prevent diversion,” including:

The “security requirement” at the heart of this case mandates that distributors “design and operate a system” to identify “suspicious orders of controlled substances” and report those orders to DEA (the Reporting Requirement). 21 C.F.R. § 1301.74(b). The Reporting Requirement is a relatively modest one: It requires only that a distributor provide basic information about certain orders to DEA, so that DEA “investigators in the field” can aggregate reports from every point along the legally regulated supply chain and use the information to ferret out “potential illegal activity.” *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf’t Admin. July 3, 2007). Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some “due diligence” and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the Shipping Requirement).

Masters Pharm., Inc. v. Drug Enf’t Admin., 861 F.3d 206, 212–13 (D.C. Cir. 2017); *see also* 21 C.F.R. §§ 1301.11, 1301.71, 1301.74.

Plaintiff contends that the Defendants failed to maintain effective controls against diversion by designing and operating a system to identify suspicious orders into Summit County between 1996 and the present, or if they implemented such a system, it was not legally compliant and/or

followed in practice, in violation of federal law thereby causing and/or contributing to the opioid epidemic. Specifically, the Defendants did not report suspicious orders that they were aware of and/or failed to stop shipments of suspicious orders.

Plaintiff contends it is facially evident that an unusually large and exponentially increasing volume of prescription opioids were shipped into Summit County, as evidenced by ARCOS data.

In order to determine which of the individual transactions is “suspicious” under federal law, the DEA would apply the system “designed and operated” by the registrant on a transaction-by-transaction basis. *See, e.g., Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206 (D.C. Cir. 2017) (applying the SOM adopted by Masters Pharmaceutical). Consequently, Plaintiff has sought discovery from each Defendant of its Suspicious Order Monitoring System (SOMS) policies and procedures since January 1, 2006, as well as discovery of all orders identified as suspicious pursuant to these SOMS. Defendants have objected to these discovery requests and, to date, none have provided fully complete and transparent responses sufficient to allow Plaintiff to accurately apply each Defendants’ own SOMS algorithm to their own transactional data.

Despite repeated requests, Plaintiff does not have sufficient documents or data to identify each suspicious order that was or should have been detected by each Defendant. Thus, the answer to this contention interrogatory is premised upon the current status of the record which has the following limitations:

- a. One or more the Defendants have yet to fully disclose transactional data for the relevant timeframe;
- b. One or more of the Defendants have yet to fully disclose the “system” (or algorithm) utilized to detect suspicious orders for the relevant timeframe;
- c. One or more of the Defendants have yet to fully disclose each suspicious order detected by the Defendants for the relevant timeframe;
- d. One or more of the Defendants have yet to fully disclose the suspicious orders reported to the DEA for the relevant timeframe; and
- e. One or more of the Defendants have yet to fully disclose the due diligence performed for each suspicious order which was ultimately shipped for the relevant timeframe.

Defendants demand Plaintiff disclose which orders it contends are suspicious without a full evidentiary record of: their policies and procedures; transactional data, including the chargeback data, EDI data, FFS data, and IMS data which Defendants were in possession of the systems and/or algorithms used by the Defendants to detect suspicious orders; the orders each of the Defendants' systems detected as suspicious; the orders reported to the DEA as suspicious; the due diligence performed before shipping a suspicious order; and expert witness discovery and testimony.

In a good faith effort to meet their discovery obligations, Plaintiff takes note of the following instructive analysis from the *Masters* Court:

More fundamentally, the key question in this case is not whether held orders qualified as "suspicious" under Masters' policies; the question is whether they qualified as "suspicious" under 21 C.F.R. § 1301.74(b). Thus, while Masters frames its challenge on this point in substantial-evidence terms, the relevant inquiry is more legal than factual: It asks how far the language of the regulation reaches. Undertaking that legal exercise, the Administrator reasonably determined that all held orders were "suspicious" within the meaning of the regulation. Section 1301.74(b) provides that "[s]uspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." Apparently tracking that regulatory language, the Computer Program held an order if: (a) that order—combined with other orders placed in the same 30-day period—requested more doses of a controlled medication than the pharmacy had requested in any of the previous six calendar months; (b) the pharmacy ordered a controlled medication more frequently in a 30-day period than it had in any of the previous six calendar months; or (c) the pharmacy's ordering pattern for a controlled medication deviated in some other notable way from its ordering pattern over the previous six months. As a matter of common sense and ordinary language, orders that deviate from a six-month trend are an "unusual" and not "normal" occurrence. It was therefore entirely reasonable for the Administrator to hold that orders held by the Computer Program met the regulatory definition of "suspicious orders" unless Masters' staff dispelled the suspicion.

Masters Pharm., Inc. v. Drug Enf't Admin., 861 F.3d 206, 216–17 (D.C. Cir. 2017) (internal citations omitted).

Bellwether Plaintiffs have previously identified multiple suspicious orders based on one or more of the following criteria: (a) met the criteria ratified in *Masters Pharm., Inc. v. Drug Enf't*

Administration, 861 F.3d 206, 216–17 (D.C. Cir. 2017);¹¹ (b) was shipped within thirty days of an order of the same national drug code (“NDC”) that was deemed suspicious and reported to DEA; (c) included the same drug family ordered by the same customer in the same month from multiple distributors; (d) was in top 10% for percentage increases for the same drug family or for total orders for the month or year; and/or (e) was of excessive size for the drug family for a customer whose prescribing significantly exceeded other similar pharmacies in the jurisdictions. Depending on the particular methodology employed, Bellwether Plaintiffs identified somewhere between 52,554 (Method 1) and 875,055 (Method 3) suspicious orders shipped into Summit between January 1996 and May 2018.

For the purposes of responding to these premature contention interrogatories, Plaintiff has not attempted to identify every possible suspicious order, nor applied every reasonable method for identifying suspicious orders. Plaintiff reserves the right to supplement or amend this answer as expert discovery commences.

In a good faith effort to meet its discovery obligations, consistent with the requirements set forth by Special Master Cohen in his Discovery Rulings 7 and 12, Plaintiff hereby identifies the orders identified in Bellwether Plaintiffs’ prior responses as suspicious orders.

¹¹ Method 1 (“Exceeding Threshold of Any of the Previous Six Months and Assuming Due Diligence”): All monthly order(s) exceeding the largest total order of any of the previous six months is considered suspicious. Method 1 assumes due diligence on the suspicious order(s), it is cleared and shipped.

Method 2 (“Exceeding Threshold of Initial 6 Months and Assuming No Due Diligence”): All monthly order(s) exceeding the largest order in any of the initial six months of the applicable dataset is considered suspicious. Method 2 assumes no due diligence on the suspicious order(s), but it is cleared and shipped. The threshold does not increase after the initial six months because each and every order shipped thereafter in excess of any of the initial six month threshold is unlawful.

Method 3 (“Previous 6 Months Threshold is Triggered and Assuming No Due Diligence”): Once an order(s) exceeds the largest order(s) in any of the previous six months of the applicable dataset all subsequent orders are considered suspicious. Method 3 assumes no due diligence on the suspicious order(s) and as a result, each and every order shipped thereafter to that individual buyer is unlawful.

Further answering, Mallinckrodt has produced consolidated unusual order reports at MNK-T1_0007730452, MNK-T1_0007730468; MNK-T1_0001810733; MNK-T1_0002079926; and MNK-T1_ MNK-T1_0001810813. In addition, Mallinckrodt has produced peculiar order spreadsheets (*see* Mallinckrodt's Supplemental Responses and Objections to Interrogatory No. 32 Ex. A); unusual order reports (*see* Mallinckrodt's Supplemental Responses and Objections to Interrogatory No. 32 Ex. B); and DEA suspicious order reports (*see* Mallinckrodt's Supplemental Responses and Objections to Interrogatory No. 32 Exs. C & D). Plaintiff contends that many of the orders identified in these documents were suspicious and were improperly shipped by Mallinckrodt.

Mallinckrodt has also identified 24 orders prior to 2009 that it determined were suspicious and were not shipped. *See* MNK-T1_0007026342, MNK-T1_000269049, MNK-T1_000301983, MNK-T1_0006805898, MNK-T1_0004268059, MNK-T1_0004267998, MNK-T1_000301986, MNK-T1_000277496, MNK-T1_000274675, MNK-T1_000269046, MNK-T1_000275736, MNK-T1_000275748, MNK-T1_000562325, MNK-T1_000259231, MNK-T1_0000259220, MNK-T1_0000475208, MNK-T1_0000475126, MNK-T1_0000296226, MNK-T1_0008590891, MNK-T1_0007202509, MNK-T1_0002363592, MNK-T1_0006442328, MNK-T1_0007730869, and MNK-T1_0007202115. In addition to these orders, Mallinckrodt has identified thousands of orders that have the same or similar identifying information as the above orders but were nevertheless shipped. *See* Mallinckrodt's Supplemental Responses and Objections to Interrogatory No. 32 at 53 and MNK-T1_0008592409. Plaintiff contends that many of these orders were suspicious and were improperly shipped by Mallinckrodt.

Plaintiff has also identified numerous documents and obtained testimony demonstrating that Mallinckrodt failed to adequately review and scrutinize suspicious orders prior to shipping them, including the deposition transcripts, deposition exhibits and custodial files of: Karen Harper,

Eileen Spaulding, John Gillies, Bill Ratliff, Victor Borelli, Steven Becker, Ginger Collier, Kate Muhlenkamp, Lisa Cardetti, James Rausch, Cathy Stewart, George Saffold, and Tiffany Rowley-Kilper. The custodial files for the above individuals also contain additional documents supporting Plaintiff's claims regarding the lack of adequate due diligence.

In addition, Mallinckrodt has identified the following prescribers and "other individuals" that it believes engaged in "inappropriate prescribing practices or other illegal acts concerning the diversion of Opioids into the illegal supply chain": Dr. Adolph Harper, Dr. Brian Heim, Dr. Ronald Celeste, Dr. Michael Tricaso, Dr. Gregory Gerber, Louis Eppinger, Patricia Arnold, Anthony H. Perry, Elizabeth Davis, James Byrge, Judy Barrows, Brittany Glass, Patricia Laughman, Adria Harper, and Tequilla Berry. *See* Mallinckrodt's Supplemental Responses and Objections to Interrogatory No. 21 at 21. A review of Mallinckrodt's documents indicates that these individuals obtained Mallinckrodt products, and that many of these individuals were well known to Mallinckrodt prior to their arrests were on Mallinckrodt "target" lists of high-prescribing doctors that it actively solicited to prescribe their products. *See, e.g.,* MNK-T1_0002159629, MNK-T1_0002282670, MNK-T1_0004814570, MNK-T1_0002719188, MNK-T1_0007068789.

Plaintiff reserves the right to supplement or amend its response as expert discovery commences, and this issue may be the subject of fully-supported and detailed expert witness opinion(s).

Interrogatory No. 28

Identify and describe any specific efforts or activities on behalf of each Manufacturer Defendant to "work[] together to inflate the quotas of opioids" (as those terms are used in Plaintiff's Second Amended Corrected Complaint in the heading above paragraph 526). For each

Manufacturer Defendant for which plaintiff can identify no such specific effort or activity, please so state.

Response:

Plaintiff repeats and reasserts its prior objections and adopts its prior responses to this Interrogatory. Plaintiff objects to this Interrogatory as vague, ambiguous, overly broad, and unduly burdensome to the extent it requests “any” specific efforts or activities on behalf of each Manufacturer Defendant to “work[] together to inflate the quotas of opioids.” Plaintiff further objects to this Interrogatory in that it seeks information uniquely in the possession of the Defendants.

Subject to and without waiving all objections, Plaintiff responds as follows: Plaintiff refers Defendants to Plaintiff’s Second Amended Corrected Complaint. Plaintiff further responds that this Interrogatory is contention discovery more appropriately answered once discovery is complete. *See* FRCP 33(a)(2). Plaintiff responds discovery continues and Plaintiff will produce a trial witness list and liability expert reports pursuant to CMO No. 1 and the Federal Rules of Civil Procedure.

Defendants used DEA quotas as a tool to drive marketing. There was a sharp increase in Purdue’s quota requests for oxycodone from 1996-2000, and a plan to obtain an increased procurement quota of oxycodone by engineering evidence showing an actual need for it. Purdue pre-sold OxyContin to distributors in bulk at a lower price, ahead of a “price increase,” to create a sharp, immediate need for product. Purdue then used the letters, or purchase agreements, from its Distributors in its application for increased quotas, arguing that Purdue’s orders were so incredibly high that a quota increase was necessary to fill its orders, and thus legitimate.¹²

¹² *See* PKY 180180232: (2001 Presentation P F laboratories/ Purdue & DEA, 08/02/2001) Presentation with DEA in support of Procurement Increases for 2001 Oxycodone in re OxyContin sales.; Includes DEA

During this time period, Capitol Hill conducted a public hearing regarding the abuse of OxyContin and Purdue's responsibility for same.¹³ Plaintiffs point to Purdue's response to the Capitol Hill public Hearing wherein the Speaker suggested the aggregate annual quota for oxycodone should be set back to 1996 levels by sending letters to all patients who were receiving OxyContin free under their Patients Assistance Program, urging these patients to contact the DEA to protest any oxycodone quota reductions.¹⁴

Purdue prodded multiple key opinion leaders (KOLs) to write to the DEA and Senators in support of Purdue and opposing quota reductions for oxycodone.¹⁵

Purdue attempted to shape publicity to give the impression that the company was partnered with the DEA in the effort to reach the right quota level; despite discrepancies between Purdue's PR and other news stories at the time.¹⁶ Despite its efforts, the DEA not only denied Purdue's

increase letters, sales projections, actual sales records, letters from Distributor Defendants stating products needs in dollar value and Quota calculations (This meeting was premeditated and it was decided by Purdue to presell to Distributors to show DEA that procurement quota was needed; *See also* PKY180180207: 2001 Letter to DEA Request to increase from 600kg to 3,795 kg Oxycodone; PKY180180202: 2001 DEA Response PF Laboratories Quo. Req. Increase Oxycodone, 04/04/2001)

¹³ *See* PKY180828378: Transcript of Minutes from May 17 2001 Capitol Hill Hearing, 05/17/2001 Capitol Hill Hearing transcript of Re. Rogers Statements on OxyContin and abuse suggest to drastically reduce Oxycodone quota to 1996 levels until the abuse and diversion problem is sorted out.

¹⁴ *See* PKY181423798 (2001 Purdue DRAFT Letter to OxyContin Patient Assistance Program Recipients Re: Potential Limitation of Oxycodone Quota 1996 Levels, 05/30/2001). Draft letter urged low income individuals to contact the DEA and Congress asking them to not cut off their OxyContin supply; scare tactics in letter warned that small reduction in Purdue Oxycodone would turn into a war on people in pain, and that 2 million patients would be without medicine.

¹⁵ *See* PKY180774462: 2010 letter Purdue KOL Dr. Gerald Aronoff to DEA in Re: Capitol Hill Hearings discussing Oxycodone Quotas, OxyContin and Purdue, 05/29/2001; *See also* PKY181383983 (2001 letter Purdue KOL Dr. Barry Eliot Cole to Senator John Ensign in Re: Capitol Hill Hearings discussing Oxycodone Quotas, OxyContin and Purdue); and PKY181383987 (2001 letter Purdue KOL Dr. Barry Eliot Cole to Senator Joe Lieberman in Re: Capitol Hill Hearings discussing Oxycodone Quotas, OxyContin and Purdue, 06/13/2001).

¹⁶ *See* PKY180628031 (2001Sheet Showing Communications Discrepancy between Public Hearing and Purdue Statements 05/17/2001; document was made and kept by Purdue with a handwritten "DEA" notation.

quota increase requests, but decided to investigate a New Jersey plant due to suspicions of improper handling of oxycodone.¹⁷ Purdue responded with heated demands for a hearing and plans to burn "unusable" oxycodone in order to create room in its existing quota for receiving new product.¹⁸

Evidence chronicles Purdue's request for annual procurement quotas increasing 700% from 1997 to 1999 as well as¹⁹ evidence of Purdue scolding the DEA for imposing quotas that interfered with Purdue's business.²⁰

Furthermore, evidence on DEA's approvals of annual and supplemental quota requests from PAR,²¹ evidence of Janssen's requests for quota increases of Tapentadol ether and the scheduling of Tapentadol,²² evidence of Mallinckrodt's efforts to obtain quota increases, or to

¹⁷ See PKY180180328 (2001 DEA Letter to Purdue RE: Denial of Increase in Oxycodone Quota. 10/11/2001; Frank Sapienza, DEA to Edward Albright, Purdue denial of request for increased Oxycodone quota dates 08/02/2001 and 09/18/2001 after review of all supporting materials due to adequate quota on hand to meet legitimate medical needs and present investigation of Totowa NJ Facility due to suspicion of oxycodone not being properly managed, stored or accounted for).

¹⁸ See PKY180180311 (Purdue response to denial of quota increase notifying DEA of disagreement requesting a hearing on decision); and PKY180180337 (2001 Letter Purdue DEA 2001 Oxycodone Allocation Intent to burn Quo. Req. Increase Oxycodone, 11/26/2001; Edward Albright, Purdue to Julie Tisinger, DEA request for 2,576 kgs Oxycodone due to intent to burn contaminated non saleable inventory).

¹⁹ See PKY180179972, including 1999 Letter P F Laboratories 2000 DEA 250 Annual Procurement Forms, 03/30/1999 250 Form and explanation of needs for Hydromorphone, Morphine, Oxycodone; documents support request for 7,449,377 more grams in 1999 of Oxycodone; Increase from 1997 quota of 2,182,855 gm of Oxycodone to 2000 quota of 14,149,309gm.

²⁰ See PPLPC023000789466; PPLPC023000789503 (2015 Letter Purdue to Christine Sannerud, DEA in re: 2015 supplemental increase request for Oxycodone providing background and justification, complaining that DEA is "constraining" ability to meet supply needs of OxyContin and ensure future of product.

²¹ See PAR_OPIOID_MDL_0001048275; PAR_OPIOID_MDL_0001048282-48284; PAR_OPIOID_MDL_0001048851 (2012 Approval of Fentanyl and Tapentadol Quota Increase Requests (Product Dev. and Transfer Quota)); PAR_OPIOID_MDL_0000416982; _0000416986; (2016 DEA approval of procurement quota increase of oxycodone for commercial purposes); PAR_OPIOID_MDL_0000417679; _0000417680 (2016 request for procurement increase of hydrocodone for commercial purposes); PAR_OPIOID_MDL_0000372172 (2013 letter from DEA to Vintage approves procurement quota increases of 134.970kg for hydrocodone and 108.440kg for oxycodone (Commercial)

²² See JAN-MS-02963918 (2016 Email from DEA to Janssen re denial of quota increase for Tapentadol; Internal email discussing DEA denying quota increase request for Tapentadol); JAN-MS-02963975; JAN-MS-02965506 (2013 DEA letter denying Janssen's 2013 Tapentadol quota request); JAN-0006-0000953

adjust quota amounts within a given allotment²³ and Mallinckrodt's increasingly urgent requests for opiates.²⁴ Teva/Cephalon's efforts to obtain increased quantities of Fentanyl, despite a rejection of its quota requests,²⁵ evidence of Activis's requests for quota increases of oxycodone and hydrocodone,²⁶ and evidence of Allergan/Barr/Watson's requests for quota increases of oxycodone,²⁷ and other examples of the opioid industry working together to attempt to increase DEA quotas.

Plaintiff reserves the right to supplement or amend its response as expert discovery commences, and this issue may be the subject of fully-supported and detailed expert witness opinion(s).

Interrogatory No. 29

(2011 Regulatory Agency Contact Report; Noramco meeting with DEA to discuss future volumes and impact on aggregate production oxycodone quota).

²³ See MNK-T1_0001317003; _0001317018; _0002257887 (2017 DEA Ltr Granting MNK Quota Req Oxymorphone, Manufacturing); MNK-T1_0001317059; _0001317090 (granting Thebaine quota increase); MNK-T1_0002331249; _0002331251; _0002258363; _0001140900; _0001140516; _0001141407 _0001309055 (multi-year requests for increase in methadone procurement quota); MNK-T1_0001312053; _0001312076; _0001312081 (documenting 2012 requests for oxycodone quota increase).

²⁴ See MNK-T1_0001506045; _0001505664; _0001505666; _0001505668; _0002220732; _0001505993

²⁵ These documents include the following communications, all originating from Cephalon: TEVA_MDL_A_00563545 (seeking third-party intercession with DEA to obtain quota increase); TEVA_MDL_A_00564282 (addressing DEA's questions to support increased quota); TEVA_MDL_A_00564289 (seeking even higher increase of fentanyl base); TEVA_MDL_A_00564291 – 64294 (requesting additional quota of fentanyl base as replacement for batch failure); TEVA_MDL_A_00564319 (requesting an additional fentanyl procurement quota with detailed justification).

²⁶ See Acquired_Actavis_00457781 (2009 Internal email informing Actavis execs of DEA approval of hydrocodone procurement increase for commercial purposes); Acquired_Actavis_00511560 - _0051156062 (2011 approval of oxycodone procurement quota increase for commercial manufacturing purposes).

²⁷ ALLERGAN_MDL_03953646 - _03953647 (documenting 2008 Watson Quota Req (Oxycodone-Commercial); ALLERGAN_MDL_03953869 (Establishing Watson 2009 Procurement Quota (Oxycodone))

Identify any specific “payments” each Manufacturer Defendant made to “physicians,” including for “participating on speakers’ bureaus, providing consulting services, and other services” (as those terms are used in Plaintiff’s Second Amended Corrected Complaint in paragraph 68). For each such identification, include (i) the Manufacturer Defendant who made it; (ii) when it was made; (iii) to whom it was made; (iv) where it was made; and (v) any evidence Plaintiff has that such “payment” was for an allegedly inappropriate purpose. For each Manufacturer Defendant for which you are not able to identify any such “payment,” please so state.

Response:

Plaintiff objects to this Interrogatory as vague, overly broad, and unduly burdensome to the extent it requests “each and every” doctor or healthcare provider who “participated” in “speaker programs” or “speakers’ bureaus.” Further objecting, Plaintiff objects to this Interrogatory as overly broad and also to the extent it seeks information that is squarely in Defendants’ possession and control. Given the late production of documents by so many Defendants, Plaintiff reserves its right to supplement, modify or amend its answers. Each Defendant has, or should have, records that identify each and every doctor or other healthcare provider who participated in “speaker programs” or “speakers’ bureaus” on behalf of or in relation to the subject Defendant. Defendants thus have far superior access to this information.

Moreover, hundreds of depositions of fact witnesses have been taken of defense witnesses and bellwether Plaintiffs utilizing hundreds of exhibits. The discovery performed to date, including depositions and extensive document productions, provides details of conduct relevant to this response. It is not practicable to specifically identify each and every payment or every speaker or every responsive document. Plaintiff reserves the right to rely upon and introduce as evidence any and all deposition testimony and exhibits addressing this topic. Also, Plaintiff’s discovery,

document review and investigation are continuing, and it reserves its right to rely upon and introduce further evidence addressing this topic.

Subject to and without waiving all options, Plaintiff supplements its responses as follows:

- From 2008 to 2013, Purdue made payments totaling almost \$231,000 for speaker programs, advisory meetings and travel costs to 11 Advocates appearing on the Purdue funded website, www.inthefaceofpain.com;
- Physicians identified by Insys Therapeutics, Inc. as having received compensation from Insys “for speaking about, endorsing or promoting SUBSYS in the State of Ohio.” (See Insys Therapeutics, Inc.’s Responses and Objections to Plaintiff’s First Set of Interrogatories);
- Physicians identified by Janssen Pharmaceuticals, Inc., its predecessor companies Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc., and its parent company Johnson & Johnson as having received compensation “for Nucynta IR and Nucynta ER speaker programs.” (See Janssen Pharmaceuticals, Inc.’s Responses and Objections to Plaintiff’s First Set of Interrogatories);
- Physicians identified through ProPublica as payments publically disclosed in Ohio from August 2013 until December 2015;
- Sales representatives from each of the Marketing Defendants visited prescribers in Summit County. Sales representatives from Purdue, Teva, Mallinckrodt, and Insys were the most frequent visitors to Summit County prescribers where, according to publicly available data, there were at least 381, 247, 149, and 138 sales visits respectively, between the third quarter of 2013 and 2016. These visits frequently coincided with payments to the prescriber for “promotional speaking,” “food and beverage,” “consulting,” “travel and lodging,” “honoraria,” and “education.” Purdue, Teva, Janssen, Endo, Mallinckrodt and Insys paid Summit County prescribers at least \$135,052 in payments associated with those categories during the time period. See <https://projects.propublica.org/docdollars/>.

Subject to and without waiving objections, Plaintiff further responds:

Name	Title	Event Description	Payment
J. David Haddox	Doctor, Committee Chair of AAPM	A “consensus” statement issued in 1997 endorsing opioids to treat chronic pain and claiming the addiction risk to patients was low.	Undisclosed amount

Russell Portenoy	Doctor, Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, Consultant to AAPM, spokesperson for Purdue	A "consensus" statement issued in 1997 endorsing opioids to treat chronic pain and claiming the addiction risk to patients was low. A quote on www.inthefaceofpain.com advocating for the need for chronic pain treatment; various speaking engagements, conferences, grants, Continuing Medical Education ("CME") programs and honorariums	>\$373,528
Lynn Webster	Doctor, co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah, spokesperson for Cephalon, Endo and Purdue	Participated in numerous CMEs; honorariums	Over \$2 million
Perry Fine	Doctor, co-chair of APS/AAPM Opioid Guideline Panel, spokesperson for Endo and Johnson & Johnson	Numerous CMEs for Endo and promotional talks for Johnson & Johnson; honorariums	\$32,017 from Johnson & Johnson; at least \$100,000 from others
Scott Fishman	Doctor, served as a board member of APF and president of AAPM	Participated in numerous CMEs; honorariums	>\$10,000
Steven Simon	Doctor at Mid-America Physiatrists in Overland Park, Kansas	Wrote prescriptions for Subsys and Fentanyl and was a designated paid "speaker" for Insys	> \$200,000 from August 2013 to December 2015
Robert Yapundich	Neurologist in Hickory, NC	Board member of the Alliance for Patient Access and paid "speaker"	> \$300,000 from 2013 to 2016

Howard Hoffberg	Doctor at Rosen-Hoffberg Rehabilitation and Pain Management Associates in Townson, Maryland	Wrote prescriptions for opioids and received "speaker" fees from Insys, Purdue and Teva	> \$175,000 from 2013 to 2016
Heather Alfonso	Nurse practitioner in Connecticut	Wrote prescriptions for Subsys in exchange for "speaker" fees from Insys.	\$83,000
Jerrold Rosenberg	Doctor in Rhode Island	Wrote prescriptions for Subsys in exchange for "speaker" fees from Insys	> \$188,000
Jeffrey Goldstein	Doctor in New Rochelle, New York	Wrote prescriptions for Fentanyl in exchange for "speaker" fees from Insys	> \$100,000 annually
Todd Schlifstein	Doctor in New York, New York	Wrote prescriptions for Fentanyl in exchange for "speaker" fees from Insys	> \$100,000 annually
Dialecti Voudouris	Doctor in New York, New York	Wrote prescriptions for Fentanyl in exchange for "speaker" fees from Insys	> \$100,000 annually
Alexandru Burducea	Doctor in Little Neck, New York	Wrote prescriptions for Fentanyl in exchange for "speaker" fees from Insys	> \$100,000 annually
Michael Frey	Doctor in Florida	Wrote prescriptions for Subsys in exchange for "speaker" fees from Insys	Unknown at this time
Jeffrey Kesten	Doctor in Boulder, Colorado	Wrote prescriptions for Subsys in exchange for "speaker" fees from Insys	\$294,000
Gordon Freedman	Doctor in White Plains, New York	Wrote prescriptions for Subsys in exchange for "speaker" fees from Insys	\$283,000
Dr. Barry Cole	Psychiatrist in Las Vegas, Nevada and founder and executive director of the American Pain Society	Speaker engagements; honorariums	>\$2,000
Dr. Michael P. Rosenthal	Acting Chief, Division of Family Medicine, Penn Medicine	Numerous speaker conferences; honorariums	>\$25,000
Dr. Seddon Savage	Doctor in New Canaan, Connecticut and former president	Statements in e-newsletters	>\$3,000

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	of the American Pain Society		
Dr. David Fishbain		Numerous speaker conferences; CMEs; honorariums; statements in e-newsletters	>\$25,000
Dr. Charles Argoff	Director, Cohn Pain Management Center, NY	Speaker conferences; CMEs; honorariums	>\$25,000
Dr. Kathleen Foley	Doctor in New York City, New York		
Dr. Myra Christopher	Doctor in Kansas City, Missouri and directed the Pain Action Alliance to Implement a National Strategy		
Dr. Steven Stanos	Medical Director of Swedish Pain Services and Medical Director of Occupational Medicine Services at Swedish Health System, WA	Speaker conferences; CMEs; honorariums	>\$25,000
Dr. Katherine Galluzzi		Speaker conferences; CMEs; honorariums	>\$25,000
Dr. Michael Moskowitz		Speaker conferences; CMEs; honorariums	>\$25,000
Dr. Grace Forde	Director of Neurological Services, North Shore Pain Services, NY	Speaker conferences; CMEs; honorariums	>\$25,000

Pursuant to Federal Rule of Civil Procedure 33(d), Plaintiff identifies the following documents containing relevant information on known payments to individuals and front groups:

ACTAVIS0875243
 ACTAVIS0290063
 ENDO00000001
 ENDO00041232
 ENDO00153633
 ENDO00444162
 ENDO00448666

ENDO00451194
ENDO00662274
ENDO00734730
ENDO00735087
ENDO00735356
ENDO-OPIOID_MDL00996815
ENDO-OPIOID_MDL01605959
ENDO-OPIOID_MDL01607843
ENDO-OPIOID_MDL01622909
ENDO-OPIOID_MDL02284410
ENDO-OPIOID_MDL02285365
ENDO-OPIOID_MDL02954028
ENDO-OPIOID_MDL02954031
ENDO-OPIOID_MDL02954051
ENDO-OPIOID_MDL04754820
ENDO-OPIOID_MDL04857592
ENDO-OPIOID_MDL05578670
ENDO-OPIOID_MDL05579494
ENDO-OPIOID_MDL05968408
ENDO-OPIOID_MDL06234663
ENDO-OPIOID_MDL06235133
ENDO-OPIOID_MDL04755213
ENDO-OPIOID_MDL01504894
EPI000648779
EPI000664121
EPI000664705
EPI000649037
EPI000649100
EPI002453701
HAD_MDL_000067430
JAN00000001
JAN-MS-00723779
JAN-MS-00787658
JAN-MS-00787662
JAN-MS-00788087
JAN-MS-00724227
JAN-MS-00275963
JAN-MS-00928088
JAN-MS-00928090
JAN-MS-00928094
JAN-MS-00928097
JAN-MS-00500135
JAN-MS-00506585
JAN-MS-00506584
JAN-MS-01246061
JAN-MS-01240530
JAN-MS-01240620

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JAN-MS-01239389
JAN-MS-00503729
JAN-MS-01245171
JAN-MS-01235809
JAN-MS-00275828
JAN-MS-00275814
JAN-MS-00505423
JAN-MS-00505426
JAN-MS-00275703
JAN-MS-00506663
JAN-MS-00502556
MNK-T1_0000661003
MNK-T1_0008440086
MNK-T1_0000218573
MNK-T1_0002084660
MNK-T1_0002181307
PPLP003477086
PPLP003465436
PPLP003477188
PPLP003468109
PPLP003464264
PPLP003464396
PPLP003464281
PPLP003476524
PPLP003464342
PPLP003476500
PPLP003464241
PPLP003476480
PPLP003476280
PPLP003476258
PPLP003476422
PPLP003476120
PPLP003476243
PPLP003476109
PPLP003476059
PPLP003475873
PPLP003476848
PPLP003475926
PPLP003475789
PPLP003475545
PPLP003475627
PPLP003475587
PPLP003475659
PPLP003475757
PPLP003475504
PPLP003475762
PPLP003475159

PPLP003475472
PPLP003474811
PPLP003475220
PPLP003475148
PPLP003474850
PPLP003474678
PPLP003474657
PPLP003474764
PPLP003474710
PPLP003474222
PPLP003473738
PPLP003474016
PPLP003473684
PPLP003473955
PPLP003473909
PPLP003473720
PPLP003474640
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PPLP003473332
PPLP003473308
PPLP003473519
PPLP003473475
PPLP003477086
PPLP003464171
PPLP003464177
PPLP003464175
PPLPC013000038227
PPLPC019000189544
PPLPC017000604922
PPLPC017000636033
PPLPC029000008967
PPLPC028000025468
PPLPC030000388174
PPLPC036000061550
PPLPC036000147128
PPLCP026000128816
PPLPC031000517249
PPLCP037000057522
PPLCP012000045701
PKY180961480
PKY180947135
PKY180785676
PKY180507584
PKY180787071
PKY180470186
PKY180790274
PKY181128168

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PKY180784295
PKY180789974
PKY180785481
PKY180572966
PKY180476707
PKY180452310
PKY180359545
PKY180622462
PKY180785211
PKY180784205
PKY180958798
PKY180671526
PKY180246201
PKY180788740
PKY180955343
PKY180515243
PKY180312563
PKY180958896
PKY180784158
PKY180279026
PKY182481437
PKY180779494
PKY180193998
PKY180606599
PKY181775488
PKY180960325
PKY181948251
PKY181944110
PKY181955637
PKY182565361
PKY180606224
PKY180958852
PURCHI-000004624
RP_000221-000741
TEVA_MDL_A_01850104
TEVA_MDL_A_01850482
TEVA_MDL_A_01850944
TEVA_MDL_A_01854966
TEVA_MDL_A_00835446
TEVA_MDL_A_01852753
TEVA_MDL_A_01088845
TEVA_MDL_A_01088810
TEVA_MDL_A_09741141
APS-MDL00000001
CHI_001208242
CHI_000371635
CHI_001208232

CHI_001207857
CHI_001207836
CHI_001207848
CHI_002298574
CHI_001208505
CHI_002303223
CHI_000930358
CHI_000930286
CHI_001208700
CHI_001208805
CHI_000433735
CHI_000928503
CHI_000929378
CHI_000930595
CHI_001173523
CHI_002048802
CHI_001978788
CHI_001193789
CHI_000430399
CHI_000434932
CHI_000433583
CHI_001030690
CHI_001164916
CHI_001208252
CHI_001164930
CHI_001164934
CHI_001216588
CHI_001026888
CHI_000437043
CHI_001213322
CHI_001164782
CHI_001213714
CHI_001214142
CHI_001212744
CHI_001208249
CHI_000544147
NHPCO_00004
PLTF_2804_000001465 – PLTF_2804_000003675

For purposes of illustration and by way of example, Plaintiff responds as follows with regard to the Teva-related Defendants:

Cephalon and/or Teva paid doctors to act as speakers in their “speaker programs” and/or “speakers’ bureaus” to promote their opioid products, including speaking and promoting those

products for off-label use and without adequately disclosing the risks associated with those products including the risks of misuse, addiction and diversion. Cephalon and/or Teva paid these doctors for training associated with these speakers' programs and/or bureaus and to speak to doctors and other healthcare providers regarding their opioid products. Such payments either were made directly by Cephalon and/or Teva, or indirectly through patient advocacy organizations or front groups which in turn would retain Cephalon and/or Teva's trained speakers and pay them out of the funds provided to such organizations and groups. (*See, e.g.*, 2/1/19 Beckhardt Depo., and Exh. 25 (TEVA_MDL_A_01174115 -TEVA_MDL_A_01174147); Exh. 26 (TEVA_MDL_A_01089593 - TEVA_MDL_A_01089596); Exh. 29 (TEVA_MDL_A_0189587 - TEVA_MDL_A_0189588)).

Cephalon and/or Teva also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Cephalon and/or Teva and other Manufacturer Defendants, these "Front Groups" – which include, but are not limited to, the American Pain Foundation ("APF") and the American Academy of Pain Medicine ("AAPM") as detailed below – generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. The evidence did not support these guidelines, materials, and programs at the time they were created, and the scientific evidence does not support them today. Indeed, they stand in marked contrast to the 2016 CDC Guideline.

Cephalon and/or Teva utilized multiple Front Groups. Several of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), the Center for Practical Bioethics ("CPB"), the U.S. Pain Foundation ("USPF") and the Pain & Policy Studies Group ("PPSG"). *See generally*,

e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep't of Health and Human Servs., (May 5, 2015). Organizations, including the U.S. Senate Finance Committee, began to investigate the American Pain Foundation to determine the links, financial and otherwise, between the organization and the opioid industry. The investigation revealed that APF received 90 percent of its funding from the drug and medical-device industry, and "its guides for patients, journalists and policymakers had played down the risks associated with opioid painkillers while exaggerating the benefits from the drugs." Within days, APF dissolved "due to irreparable economic circumstances."

Another front group for Cephalon and/or Teva was the American Academy of Pain Medicine. With the assistance, prompting, involvement, and funding of Cephalon and/or Teva, along with other opioid manufacturers, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Cephalon and/or Teva's deceptive marketing of chronic opioid therapy. AAPM received substantial funding from opioid manufacturers.

Examples of documents reflecting responsive information concerning the payments to Cephalon and/or Teva speakers and direct payments can be found at:

- TEVA_MDL_A_10029040 - TEVA_MDL_A_10029045
- TEVA_MDL_A_07116813 - TEVA_MDL_A_07116816
- TEVA_MDL_A_09068993 - TEVA_MDL_A_09068994
- TEVA_MDL_A_01399870 - TEVA_MDL_A_01399872
- TEVA_MDL_A_13583363 - TEVA_MDL_A_13583364
- TEVA_MDL_A_07546996 - TEVA_MDL_A_07547019
- TEVA_MDL_A_00978599 - TEVA_MDL_A_00978601
- TEVA_MDL_A_00784866
- TEVA_MDL_A_03413816
- TEVA_MDL_A_02199962
- TEVA_MDL_A_07116816

With respect to Endo, Plaintiff states as follows:

As part of the post-launch plan for Opana ER, Endo introduced a Promotional Speakers Program to support the new product. The objective of the program was to “educate physicians on the benefits and proper use of Oxymorphone” and to “encourage trial of Oxymorphone with prescribers of long acting opioids.” ENDO-CHI_LIT-00551008. The plan was to hold a “series of promotional meetings with high prescribers of strong opioids.” *Id.* According to a market update report from October 2006, 15 health care providers were trained as speakers and 65 additional health care providers signed up for programs slated to run from October 27-29, 2006. ENDO-CHI_LIT-00547005.

The following year, 2007, saw 4,630 attendees participate in the speaker program. EPI000300652. Endo determined that the return on investment in these programs turned positive 8-12 weeks after the program. *Id.* Cognizant of the high cost per attendee, Endo sought to reformat its program to focus on a patient case format, and target other health care professionals such as nurses and physician assistants, amongst other changes. *Id.*

By 2009, Endo developed three different speaker programs: a Field Driven Speaker’s Bureau, a Regional Opana Prescriber Education Program (“ROPE”), and a Faculty Forum. ENDO-CHI_LIT-00166206. Through a variety of peer-to-peer formats, the goal was to increase awareness and clinical discussion of Opana ER as a preferred therapy to manage the complexities of pain. ENDO-CHI_LIT-00023245. The Field Driven events were regional in nature and targeted markets of greatest potential. *Id.* Internal projections anticipated approximately 21,000 attendees. *Id.* According to the 2009-2013 Opana Brand Tactical Plan, the estimated investment in the program was \$10 million dollars. *Id.*

The ROPE speaker events were fewer in number but larger events generally, with anticipated attendance of 150 healthcare professionals or more. ENDO-CHI_LIT-00023245. The goal of this program was to increase awareness and clinical discussion of Opana ER as a preferred

therapy to manage the complexities of pain. *Id.* The content of ROPE events would revolve around case study slide sets and focus on converting patients to Opana ER. *Id.* The initial plan for this speaker series called for 10 events with an estimated budget of \$593,525. *Id.*

The Faculty Forum series supported Endo's trained speakers. These forums were tailored by local sales reps according to their local territory needs, leading to a variety of meal programs, roundtable discussions or teleconferences. EPI000300652. These events included speaker trainings and targeted field events. ENDO-CHI_LIT-00032734. Endo invested \$3,816,576 in the series and launched the initiative in 2008. EPI000300652. Results showed that 260 speakers were trained in 2008, 1105 programs were completed and 5,200 hcp's attended. ENDO-CHI_LIT-00062030. In 2008 approximately \$6 million was invested in the Faculty Forum speaker program. *Id.* The following year Endo dedicated \$6.4 million to the Faculty Forum program. ENDO-CHI_LIT-00023297. There were 1,000 programs planned for 2009 with 159 opinion leaders trained and 55 additional hcp's scheduled for training. ENDO-CHI_LIT- 00062030. Many KOL's came on board as speakers and participated as trainers and speakers in the various speaker programs. In May 2013, following the FDA's denial of Endo's Citizen Petition, Endo cancelled all remaining promotional speaker programs. ENDO-OR-CID-01330991. According to meeting minutes from a 2013 Pain Business Unit meeting held at the end of 2013, no speaker programs were scheduled for 2014. EPI000925433 at *34.

Endo understood the importance and influence of KOLs to promote the use of opioids generally, and early on began developing influence maps of regional and local KOLs to support EN3202, as reflected in a January 2004 Monthly Business Report. ENDO-CHI_LIT-00552983. This was later integrated into Endo's strategy of "Building Champions" for Opana ER. ENDO-OPIOID_MDL-00848258. The goal was to "understand who and where the pain medicine though

t leaders are”; engage national thought leaders in oxymorphone clinical studies, as advisors, as speakers”; and “utilize national advocates to reach regional and local thought leaders. *Id.*

Cultivating Opana advocates and KOLs to encourage adoption of Opana ER’s broader use of opioids to treat chronic pain featured prominently in Endo’s pre-launch planning for the Opana franchise. Pre-launch, Endo devised a program to develop “Opana Champions”. END00000923. “Champions” would be a part of clinical advisory meetings, marketing advisory boards and promotional breakfast meetings” *Id.*

Periodically, Endo would rank KOLs, referring to it internally as a KOL mapping project. ENDO-OPIOID_MDL-01725812. The project involved determining the KOL’s overall impact and assigning them to different categories. Endo examined whether their impact was regional or national in nature, the amount of dispersion across states and the number of people nominating the KOL for their place on the KOL mapping project. ENDO-OPIOID_MDL-01725813. Below are the categories and criteria as identified by Endo in 2007:

Criteria	Concentration	Direct Nominations
National High	Greater than 10 dispersed States	15 or more
National Low	Less than 10 dispersed States	9 or more
Regional High	States closely concentrated	8 or more
Regional low	States closely concentrated	Less than 8
Local High	80% of nominations within 50 miles	5 or more
Local Low		Less than 5

Overall, the mapping project allowed Endo to identify the Top 200 KOLs for the Opana.

Endo utilized KOLs in a variety of functions supporting Opana. KOL targets were defined as “physicians who are research focused, national level influence, speakers and research publishers

in the medical community.” ENDO-OPIOID_MDL-00627335. Internally, these physicians were referred to as KOLs, or Therapeutic Experts (“TE”). ENDO-OPIOID_MDL-00665227. Members of the Clinical Affairs department, internally referred to as Clinical Affairs Managers (“CAMs”), were responsible for identifying and building “effective working relationships with regional and national TEs in Endo’s area of therapeutic interest.” ENDO-CHI_LIT-00237750. In 2008, Endo identified 674 TEs by topic: 187 experts in osteoarthritis, 128 experts in migraine/neuroscience, and 359 Chronic Pain and Moderate-to-Severe-Chronic Pain experts. *Id.* In 2012, Endo reorganized the department and the former CAMs were retitled to Medical Science Liaisons (“MSLs”). However, the MSLs assignments remained the same as before, including communicating with and developing Endo’s KOL relationships. *Id.*

KOLs and TEs participated in marketing panels, pain task forces and speaking engagements. ENDO-CHI_LIT-00547230, ENDO-CHI_LIT-00217549. They also developed materials supportive of the use of long-acting opioids generally. A 2008 Clinical Affairs presentation listed the following examples of development initiatives with Endo’s KOLs: “Portenoy/Fine *Clinical Guide to Opioid Analgesia* handbook”; “Dworkin – IASP closed roundtable/publications on new data/developments in Neuropathic Pain”; “Saper, Silberstein et al – establishment of ICD-9 code for MM”; ‘Fishbain et al – *Pain Medicine* supplement on oxymorphone”; ‘Portenoy/Pasternak/Jackson – Opioid rotation roundtable & upcoming publication in “*J Pain Symptom Manage*”; and “Fishman & Dahl – national FSMB/state pain initiative project.” ENDO-CHI_LIT-00237750.

Documentation requesting that the doctor be designated as a KOL had to be submitted for review by marketing and medical affairs for approval. ENDO-CHI_LIT-00515301. Exceptions to the Fair Market Value payment restrictions were commonly requested for doctor’s identified as

KOLS. ENDO-CHI_LIT-00217550. These exceptions allowed Endo to pay the KOL in excess of the uniform fee established for other non-KOL healthcare providers.

On May 8, 2012, pursuant to an investigation into the relationship between opioid manufacturers and non-profit health care organizations, the Senate Finance Committee asked Endo to disclose the amount of funding it had paid to prominent KOLs who advocated for the use of opioids, including Russell K. Portenoy, M.D., Scott M. Fishman, M.D., Perry G. Fine, M.D., Lynne R. Webster, M.D., Rollin M. Gallagher, M.D., Bill McCarber, M.D., Martin Graboys, M.D., and Myra Christopher, M.D. ENDO-OR-CID-00806002. In Endo's July 6, 2012 response, it disclosed the following total payments: \$73,855.10 to Dr. Portenoy from 1999-2002 for Pain Education, Honorarium and expense reimbursement from 1999-2002; \$8,000 to Dr. Fishman from 2002-2004 for Pain Education; \$36,881.20 to Dr. Fine for pain education, outside contracting services, project consultant from 2002-2007; \$22,500 to Dr. Gallagher for pain education and project consulting from 2001-2005; \$45,193.30 to Dr. McCarberg for pain education, honorarium, expense reimbursement and sales support from 2001-2006; and \$4,000 to Dr. Graboys for pain education in 2004 and 2006. ENDO-OR-CID-00754369. Importantly, Endo reported that the disclosures were for direct payments by Endo and noted the following limitation of its funding disclosure: "Indirect payments to physicians, through third party vendors for events such as conferences, speaker programs, or seminars, may not be identifiable in the SAP system. Accordingly, payments to the individuals listed in request 1(b) by third-party vendors engaged for services by Endo may not be reported, as Endo lacks the systems infrastructure to readily track and report payments made to the individuals through third party vendors." *Id.*

While direct payments may not have been substantial, Endo regularly employed third parties to facilitate the recruitment and payment of KOLs for various promotional and education programs. For instance, in association with a May 2011 NIPC Dinner Dialogue engagement, the

APF forwarded a Faculty Responsibilities Agreement to Dr. Perry Fine in the amount of \$3,000, for his speaking services at the dinner. CHI_001212779. Notably, this payment was not included in the fee disclosure made by Endo to the Senate Finance Committee, as it was within the “indirect” payment category expressly disclaimed by Endo. ENDO-OR-CID-00754369.

Notable KOL’s Endo collaborated with include, but are not limited to: Russell Portenoy, MD; Ray Sinatra, MD; Betty Ferrell, MD; Gilbert Fanciullo, MD; Bruce Nicholson, MD; Charles Argoff, MD; Martin Angst, MD; Paul Christo, MD; Lynn Webster, MD; Richard Rauck, MD; Alan Matsumoto, Md. ENDO-CHI_LIT-00547230. In the Midwest Region, notable KOLs included Dr. Schertzinger (West Chester, OH), Dr. Otten (Columbus, OH), Dr. McGowan, Dr. Hailey, Dr. Peppler, Dr. Scheperle, Dr. Mann (Columbus, OH), and Dr. Sueholtz. ENDO-OPIOID_MDL-00627336. In 2013, one presentation boasted “Strong relationships with 1,000 Therapeutic Experts (KOLS).” ENDO-OPIOID_MDL-00665227.

On February 15, 2013, Endo submitted a labeling supplement proposing additions to the label including “pre-and postmarketing data from in vitro and in vivo abuse potential studies to the DRUG ABUSE AND DEPENDENCE section of the Package Insert.” ENDO-OR-CID-01174358. On May 10, 2013, the FDA denied the application and highlighted the following concerns about the formulation:

no pharmacokinetic studies measuring serum concentrations following nasal administration or assessing the ability to insufflate have been conducted. Additionally, no human abuse liability studies examining abuse by the nasal route of administration have been conducted. The ease with which the product can be manipulated, and the ease with which oxymorphone can be extracted from the manipulated product, are not consistent with a formulation that would provide a reduction in oral, intranasal or intravenous abuse of Opana ER. *Id.*

The FDA also cited concerns with the post marketing data Endo submitted in support of the label change. The FDA found,

[t]he postmarketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse of Opana ER due to:

- the short period of time represented
- the overlap of prescriptions for both the original formulation of OPANA ER and reformulated OPANA ER during the first quarter of the reporting period
- the continued availability of original OPANA ER throughout the reporting period
- the possible misclassification of the original and reformulated products based on the similar appearance of the two products.

ENDO-OR-CID-01174359.

As part of the post-launch plan for Opana ER, Endo introduced a Promotional Speakers Program to support the new product. The objective of the program was to “educate physicians on the benefits and proper use of Oxymorphone” and to “encourage trial of Oxymorphone with prescribers of long acting opioids.” ENDO-CHI_LIT-00551008. The plan was to hold a “series of promotional meetings with high prescribers of strong opioids.” *Id.* According to a market update report from October 2006, 15 health care providers were trained as speakers and 65 additional health care providers signed up for programs slated to run from October 27-29, 2006. ENDO-CHI_LIT-00547005.

With respect to Mallinckrodt, Plaintiff states as follows:

Mallinckrodt maintained a detailed “target” list of KOLs with respect to specific products or treatment areas. Mallinckrodt has not, however, produced a comprehensive list. For example, MNK-T1_0002370786 lists the Addiction Treatment KOLs as of May 2014. Other documents contain KOLs for Exalgo (*see, e.g.*, MNK-T1_0000858528 (2009) and MNK-T1_0002287371 (2010)). MNK-T1_0006314623 contains MSL recommendations for publications and ISR advisory boards for Exalgo as of February 2010. In terms of the events at which individual KOLs spoke, Mallinckrodt is in possession of this information but has not provided it.

The amounts paid to each KOL is information that is solely in Mallinckrodt's possession, and to date Mallinckrodt has been unable or unwilling to provide this information in a usable form. Mallinckrodt has produced over two thousand pages of individual grant documents. *See* MNK-T1_007765741 – MNK-T1_7775776. In addition, Mallinckrodt has produced a "payment report" from its J.D. Edwards database. *See* MNK-T1_008005740. This payment report consists of over 199,000 line entries, and appears to encompass every third party that Mallinckrodt did business. For many entries there is no description of the service being provided. Another document, MNK-T1_0001499354, lists 2010 and 2010 budgets for speakers' bureaus but does not provide any break-down of payments. Neither Mallinckrodt's 30(b)(6) designee on the topic of KOL and front group payments, nor Mallinckrodt's senior finance director, could provide an aggregate break-down of payments. *See* 30(b)(6) Deposition of Kevin Webb and Deposition of Jeff Kilper.

With respect to Purdue, Plaintiff states as follows:

Dr. Portenoy and Dr. J. David Haddox of Purdue were both part of the group that drafted the 1995 APS-AAPM Consensus Statement on Quality Improvement Guidelines for the Treatment of Acute and Cancer Pain. PDD1501803068 at -74. Also among that group was David Joranson of the University of Wisconsin's Pain & Policy Studies Group ("PPSG"), along with Dr. Daniel Carr and Dr. Richard Payne, who would both become prominent KOLs (especially tied to Janssen). PDD1501803068.

Portenoy had a relationship with Purdue as early as August 1997, as shown by a letter requesting a \$100,000 grant for initiatives at Beth Israel Medical Center ("Beth Israel"). PKY180772092. Portenoy mentions that other "industry leaders" have responded positively to his request. Beth Israel received millions in industry funding over the years. ENDO-OPIOID_MDL-01610298.

Dr. Haddox and Dr. Portenoy had a close, collegial relationship, emailing each other directly about meetings, papers, grants, and various work matters. PPLPC020000005715 (Portenoy requests names of doctors who can speak to negatives of opioid use, Haddox responds); PKY180650211 (Haddox requests Portenoy give presentation covering treatment of non-cancer pain); PKY180650171 (Haddox requests Portenoy presentation differentiate addiction terminology); PDD8801291781 (Portenoy discusses opiophobia for Purdue); PPLPC025000013093 (Haddox requests dinner meeting at conference); PPLPC025000014468 (Haddox invites Portenoy to participate in educational task force); PKY182717470 (Haddox thanks Portenoy for commentary on panel). Haddox was connected to the then-new ABPM certification and strongly encouraged Portenoy to take and promote the examination. PPLPC025000005590. The goal was to “certify that physicians possess requisite knowledge to practice safe, effective, and ethical pain medicine.” PPLPC025000005590.

Portenoy ultimately agrees to take the ABPM certification, telling Haddox that Purdue “changed the world” in cancer pain management and should do it again with respect to “these areas” that they recently discussed. PPLPC025000005606 (the treatment of chronic, non-cancer pain). Documents from both Janssen and Purdue demonstrate they viewed chronic, non-cancer pain as an opportunity to expand sales. Haddox eventually writes Portenoy’s required letter of recommendation for the ABPM certification. PPLPC0250000014968; PPLPC0250000015981.

Portenoy also requested a grant for Beth Israel pain management initiatives. PPLPC025000005606. Beth Israel’s Development Director also emailed Haddox, calling Haddox and Portenoy “crusader[s] with a cause” and attaching a proposal for the Project on Pain and Chemical Dependency, focusing on the “true risk of addiction” when using opioids in treatment of chronic, non-cancer pain (among related topics). PPLPC025000005743-44. Haddox emailed Portenoy several times, assuring him that he is looking into the grant funding, sometimes

inquiring what other companies are offering. PPLPC025000005725, PPLPC025000005759, PPLPC025000006722, PPLPC025000007427.

Haddox also helped Portenoy put together a listserv for Beth Israel's Project on Pain and Chemical Dependency. PPLPC025000005739-41. The initial email included various doctors, government insiders, and PPSG member Joranson. PPLPC025000005739. Portenoy emails the listserv at one point, lamenting that "use of opioids relies so strongly on personal impressions" because of lack of research. PPLPC009000009824.

Dr. Passik joins Portenoy in requesting money from Purdue in February 2001, stating that they need \$1.5 million from industry partners to fund the Project on Pain and Chemical Dependency. PPLPC025000019244. In the same email, Passik notes that he wrote a letter to a journal discussing diversion and stating that OxyContin was not the real problem; he also mentioned giving a talk for Janssen in which he defended OxyContin. *Id.*

In April 2001, Portenoy sent a letter to Goldenheim at Purdue, recommending an "unusual" partnership between industry competitors, along with academic medicine. PKY180702082. He envisions input from regulatory agencies and law enforcement, and he requests a grant of \$300-\$500k annually. *Id.*

After April 2001, after Portenoy sends the Goldenheim letter and the documents on which Portenoy appears center more around various advocacy groups and around Janssen.

Around August 2001, Portenoy became co-chair of The National Pain Education Council ("NPEC"), which Janssen spent millions to create to handle its unbranded marketing, including doctor training programs and other initiatives. Richard Payne was his co-chair (with ties to the Robert Wood Johnson Foundation), and the group included a member of JCAHO and a member of PPSG, among others. JAN-MS-00306713. According to January 2003 meeting notes, Drs. Payne and Portenoy would be paid "\$15M" individually and "\$25M" to their respective

institutions in honorarium. JAN-MS-00312977. In late 2002, Purdue was approached about NPEC funding. PPLPC01900029262; PPLPC01900029246.

One of NPEC's main goals was to position long-acting opioids as preferred therapy for the treatment of chronic pain. JAN-MS-00787624. By November 2003, NPEC's website was getting more than 5,000 views a day some days, 57% of visitors were doctors, half were repeat visitors, and 29% returned more than six times. JAN-MS-00315204.

Portenoy met with the DEA in his NPEC capacity. JAN-MS-00777576. By February 2002, Portenoy advises Janssen's consultants, Discovery International, that NPEC should not seek DEA endorsement; rather, they should seek it from Joranson's group, which would encompass the DEA and FDA. JAN-MS-00312347. Meetings between NPEC and DEA take place at APS. *Id.* NPEC also appears to have engaged the Government Accounting Office about Medicaid reimbursement. JAN-MS-00315240

The NPEC meetings appear to converge with meetings of members of the "Pain Forum" and the "RX Action Alliance." These meetings continued at least through March 2004, with members of PPSG, APF, RWJF/Last Acts, and the DEA. CHI_001703128; CHI_001703770. Portenoy edited a publication by DOJ, RWJF, and PPSG regarding diversion. WIS_PPSG_000668; WIS_PPSG_000870.

APF sponsored a "corporate roundtable" with Purdue, Janssen, Endo, and other corporations, which Portenoy attended. CHI_000185456.

During this time, Portenoy continued to advise both Purdue and Janssen on various matters. PKY181288804 (requesting funding for documentary and online symposium); MDL_ASPE_000000225 (randomized controlled trial of oxycodone sponsored by Purdue and conducted by Beth Israel); E513_00002943 (consulting on a drug study); PPLPC028000089676 (advising Purdue of contact to consult on buprenorphine); JAN-MS-00725920 (advising Janssen

on AP-48 product). He also had interaction with Endo and Teva. ENDO-OPIOID_MDL-01766731(Portenoy and Fine agree to assist with opioid handbook); TEVA_MDL_A_08240715 (Portenoy answers questions on Actique study).

Portenoy's resume demonstrates his positions in various front groups and their committees (including APF, APS, AAPM, Last Acts/RWJF), awards he received from industry, and publications (showing evolution from cancer to non-cancer pain treatment). RP_0202712.

Transcripts of Portenoy's testimony before governmental entities provide further evidence of the RP_021306 (Prescription Drug Abuse Hearing before AG Blumenthal); RP_021194 (OxyContin: Balancing Risks and Benefits Hearing before US Senate).

PAIN IS "UNDERTREATED"

An article written by the APF demonstrates that surveys suggesting that pain is "undertreated" were produced by the pharmaceutical companies – and for the purpose of gaining media placement and influencing consumer attitudes. JAN-MS-02325533.



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**Review of American Pain Surveys
Designed to Gain Media Placement and/or
Influence Consumer Attitudes**

1994-Present
Prepared by the American Pain Foundation
May 2002

Summary

The following is a review of nine US pain surveys, arranged by date, that were conducted over the last seven years. All but one—*Pain in America: A Survey of American Attitudes Toward Pain*, sponsored by the Mayday Fund—were commissioned by pharmaceutical companies and developed by public relations agencies for the purpose of influencing consumer attitudes and promoting a particular products or a class of drugs. Several of these surveys were done in collaboration with nonprofit organizations. Some of the surveys had a particular focus (e.g., effect of pain on the elderly, pain and work, pain and gender differences, etc.).

The APF researched the all the surveys conducted by the industry and determined them to be biased. JAN-MS-02325533 at -34.

To date, all but one (the Mayday survey) of the general, non-disease specific, national pain surveys were commissioned by individual pharmaceutical companies for the purpose of creating awareness about pain and (indirectly) promoting a product or class of drugs. The most commonly used method to accomplish this was to craft questions designed to demonstrate the dangers, or lack of effectiveness, of other types of drugs or delivery systems. . . . None of the surveys were initiated by nonprofit pain advocacy or professional organizations or epidemiological research organizations. Nonprofit organizations were often involved to lend credibility to the studies and increase likelihood of media coverage. Reputable polling firms (Louis Harris, Roper Starch, etc.) were employed to conduct surveys to give credibility to them.

JAN-MS-02325533. The APF report concludes that there is a need for a large-scale, unbiased pain survey, conducted by epidemiologists. JAN-MS-02325533 at -35. "Everyone working to improve pain management . . . needs reliable and current statistical data to inform and guide their work. As

the old adage goes, *you cannot manage what you cannot measure.*" JAN-MS-02325533.

The studies that APF researched include the following:

1. 1995 *National Pain Survey* by McNeil Pharmaceutical: "The key finding was that the majority of patients were reluctant to take certain types of drugs because of fears about side effects such as gastrointestinal bleeding and potential for addiction." *Id.* at -36. The survey coincided with the 1995 FDA approval and launch of Ultram (a version of which is co-promoted by Purdue).
2. 1996 *Pain and Absenteeism in the Workplace* by Ortho McNeil Pharmaceutical: "The study was designed to promote Ultram . . ." Its key finding was that untreated pain was a detriment to business. *Id.* at -36.
3. 1997 *Pain and the Older Americans Survey* by Ortho McNeil Pharmaceutical: Key finding was that a large number of older Americans take too many NSAIDS and end up with gastrointestinal problems. The study targeted potential users of Ultram. *Id.* at -37.
4. *The 1999 National Pain Survey* by Ortho McNeil Pharmaceutical: The survey is a follow-up on the 1994 survey that examined "the analgesic dilemma," not included in this APF report, which looked at patient fears about side-effects, addiction, and prescribing practices. *Id.* at -40. Among key findings: 9 in 10 physicians were concerned about opioid side effects, including addiction. *Id.* An email within Janssen on October 29, 1999 regarding KOL interviews is potentially related.
5. 2000 *Pain in America: A Research Report* by Merck & Company: Among the key findings, nine in ten Americans suffer from regular pain. *Id.* at -41.
6. 2000 *Chronic Pain in America: Roadblocks to Relief* by Janssen Pharmaceutica, the American Pain Society, and the American Academy of Pain Medicine: This survey was conducted between November 1998 and January 1999. Its stated purpose was to heighten awareness among consumers and the medical community on the issue of chronic pain and the need to treat it aggressively. *Id.* at -43.
7. 2000 *A Survey of Pain in America* by Purdue Pharma (Partners Against Pain): The survey was designed specifically to promote OxyContin. *Id.* at -45.
8. 2001 *Gender Attitudes Toward Chronic Pain* by Purdue Pharma (Partners Against Pain) and the National Women's Health Resource Association. *Id.* at -46.
9. 2002 *Pain in Maryland* by Medtronic, Abbott, the American Pain Foundation and the Maryland Pain Initiative. *Id.* at -47.

Purdue internally recognized that later surveys by Janssen were "clever marketing."

PLPC009000079874.

Shortly before the above report was published, the executive director of the APF and Dr. Richard Sackler of Purdue had a direct relationship. On February 11, 1999, the executive director of the APF, Jim Guest, emailed Dr. Richard Sackler, thanking him for a \$250,000 contribution and alerting him to impending legislation. PPLPC026000000291. Guest and Sackler discussed that Guest approach Janssen to leverage a similar grant. *Id.* Guest followed up on it, because the APF approached Janssen asking for \$250,000. JAN-MS-01052077. *See also* PPLCP018000004292 (email with evidence of funding from Ortho-Biotech, APS, Knoll, and Endo).

By August 5, 2000 Purdue expected return on that financial support for APF. Robin Hogen emailed Haddox about APF executive director Jim Guest, saying “[i]f they want our bucks (and they honestly cannot survive without industry support) they are going to have to learn to live with ‘industry’ reps on their board. I don’t think they can expect huge grants without some say in governance.” PPLPC025000012558. Guest discusses with Sackler that the APF does not want industry connections on the board because it wants to avoid the appearance of impropriety – while keeping Sackler informed about the APF’s every move.

Guest’s email also referenced the Pain Relief Promotion Act, stating that the Pain Care Coalition (APS, AAPM, ASA) specifically asked for the declaration that this is the “Decade of Pain Control and Research.” PPLPC025000012558. June Dahl of the Pain & Policy Studies Group was also involved. PPLPC025000012558.

Pre-2001 Guidelines

Prior to 1994, physicians treated cancer pain according to the World Health Organization’s (“WHO”) three-step analgesic ladder. *See* PKY183222319 at -22. Step 1 of the WHO ladder represented treatment of mild pain with aspirin, acetaminophen, and NSAIDS. PKY183222319. Step 2 of the WHO ladder represented moderate pain, treated with “weak” opioids like codeine,

oxycodone, and hydrocodone. PKY183222319. Step 3 represented severe pain, usually treated by either fentanyl or morphine. PKY183222319.

In 1994, the Agency for Health Care Policy and Research ("AHCPR") adopted Clinical Practice Guidelines for the Treatment of Cancer Pain. The AHCPR is a branch of the Department of Health and Human Services ("HHS").

Purdue recognized that guidelines could be used to sell MS Contin and partnered with AHCPR to distribute the guidelines. PDD1706039146. Indeed, Purdue timed the launch of its Partners Against Pain program to coincide with the release of the AHCPR guidelines. PKY180628795.

March 7, 1994

F-D-C REPORTS — "The Pink Sheet"

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PURDUE FREDERICK "PARTNERS AGAINST PAIN" PROGRAM LAUNCHED TO COINCIDE WITH AHCPR GUIDELINES; PURDUE FREDERICK SALES FORCE WILL DISTRIBUTE GOVERNMENT GUIDES

Purdue Frederick is incorporating clinical practice guidelines from the Agency for Health Care Policy & Research into a promotional/patient education campaign for pain control.

PKY180628795. In a Quarterly Report about MS Contin from Michael Friedman to the Sacklers,

Mr. Friedman recorded:

These guidelines are a selling tool that we can use. . . . In anticipation of the publication of the AHCPR guidelines we trained influential physicians on how to deal with media and enlisted their support for our public relations campaign. Two days before the guidelines were published our press-kit was sent to approximately 600 reporters and our video news release and sound tape was sent to over 150 TV and radio stations . . . We have numerous reports of our product being displayed in a favorable light during press coverage of the AHCPR guidelines.

Id. PDD1706039146 at -47.

The Pink Sheets, a daily business publication, reported that "[t]he Purdue Frederick adoption of the AHCPR guidelines into its program is one of the most direct uses of a recommendation from that agency by a pharmaceutical maker." PKY180628795. The University

of Wisconsin, home to the soon-to-be-formed Pain & Policy Studies Group, was also involved in creation of the guidelines. As part of the AHCPR guideline distribution, one of AHCPR's cancer pain board members, Charles Cleeland, PhD, of the University of Wisconsin Medical School, authored an article about the undertreatment of cancer pain, published in The New England Journal of Medicine. PKY180628795. Also involved in the Purdue program launch were two cancer specialists from the Fox Chase Cancer Center in Pennsylvania, both of whom were consultants to the AHCPR in creating the guidelines: Michael Levy, Md/PhD, and Pamela Kedziera, RN. PKY180628795.

Purdue recognized that the AHCPR guidelines were favorable to OxyContin in that they 1) "reinforce [the] principle of tailoring pain medications to the individual patient by titrating upward before switching, 2) "using adjuvant agents," and 3) "treating specific types of pain with individual agents," as opposed to mixing, for example, opioids and NSAIDs. PKY180287212 at -20. "The dosing flexibility offered by OxyContin is consistent with these guidelines as a Step 3 agent." PKY180287212

Purdue's intent, however, was to position OxyContin in Step 2 of the WHO ladder, for more moderate, non-cancer pain, and to push fentanyl to the most extreme of Step 3. *Id.* at -22, 25-29. Purdue intended to do this by "engineering" successful trials. *Id.* Purdue also planned a play, direct mailers, and certification programs for oncology nurses (through a grant to ASPMN), and a media roundtable (using representatives of relevant associations for "third-party credibility"), and press information packages. PKY180287212.

By 1995, Purdue was watching the APS guideline process. PDD1501803068. An unidentified Purdue custodian printed and highlighted a copy of the 1995 APS Consensus Statement, "Quality Improvement Guidelines for the Improvement of Acute Pain and Cancer Pain." PDD1501803068. The highlighted portions read:

By making the magnitude of the problem [of undertreated pain] apparent and committing the institution to change, pain treatment QI programs can provide a foundation for a multifaceted approach that includes education of clinicians and patients, design of informational tools to minimize errors in prescribing, and improve coordination of the process of assessing and treating pain. . . . The targeted outcome was that each patient would receive timely and optimal doses of analgesic drugs.

PDD1501803068 at -68-70. The article also notes that the draft guidelines were circulated to the full membership for comment. PDD1501803068 at -70. The drafting committee was composed of the following members: Mitchell B. Max, MD (National Institute of Health/National Institute of Dental Research); Marilee Donovan, Ph.D., RN (Kaiser Sunnyside Medical Center); Christine A. Miaskowski, PhD, RN (University of California); Sandra E. Ward, PhD, RN (University of Wisconsin); Debra Gordon, MSN (University of Wisconsin); Marilyn Bookbinder, PhD, RN (Memorial Sloan-Kettering Cancer Center); Charles S. Cleeland, PhD (University of Wisconsin); Nessa Coyle, RN, MS (Memorial Sloan-Kettering Cancer Center); Margaret Kiss, MS, RN (Memorial Sloan-Kettering); Nora Janjan, MD (University of Texas M.D. Anderson Cancer Center); W. Thomas Edwards, PhD, MD (Harborview Medical Center). Contributions from the following people were also noted: Margo McCaffery, RN, MS; Carol Howe, MSN; Susan Hagan, BSN, MS; Mary Layman Goldstein, RN, MS; Susan Derby, RN, MS; Mary Born, RN, MS; Betty Ferrell, PhD, RN; Jan Frandsen, RN, MS; Daniel B. Carr, MD; Sri Vasudevan, MD; Russell Portenoy, MD. PDD1501803068 at -74.

By May of 1998, the American Geriatric Society published new guidelines for treating pain in the elderly, and Janssen was definitely involved. JAN-MS-00270843. An email was sent around Janssen, specifically the Ortho-McNeil division (then responsible for Ultram), inquiring as to whether the company had any influence over the AGS guidelines. JAN-MS-00270843. The answer was that Ortho-McNeil did not but that “[i]t was all driven by the Tylenol brand.” JAN-MS-00270843. “[W]e were invited to join the MCP folks at a final meeting at AGS . . . I’d inquired

as to whether we could somehow get ULTRAM also considered for inclusion in these g'lines, and unfortunately was told that their scientific advisors had already signed off on them (the ULTRAM brand was aware of this)." JAN-MS-00270843. Because of coverage on NSAIDS and undertreatment of pain, the Ortho-McNeil strategy going forward was get media to discuss effective treatments for chronic pain (which would presumably include ULTRAM and other opioids). JAN-MS-00270843.

Purdue and Ortho McNeil were at the time meeting to discuss Ultram. PPLPC018000002278. Friedman's notes from an April 1997 meeting (apparently THE meeting in which the two agreed to work on Ultram) reveal that Ortho McNeil sought to position Ultram as an alternative to "dangerous" NSAIDS. The two sides discuss broader pain policy, but primarily with respect to scheduling and the FDA, not guidelines.

From August 23-25, 1998, Purdue was looking at pain guidelines. See PKY183028750, PKY183028698, PKY183052486.

The 2001 JCAHO Guidelines & Model State Guidelines

The WHO, AHCPR, and APS guidelines "had not worked," meaning they were not being uniformly implemented by healthcare providers. David Baker, MD, MPH, *The Joint Commission's Pain Standards: Origins & Evolution*, The Joint Commission (May 5, 2017), https://www.jointcommission.org/assets/1/6/Pain_Std_History_Web_Version_05122017.pdf. Under those guidelines: "Physicians were 'rarely held accountable' for inadequate pain control, and they had not implemented systems to address the problem." *Id.*

Purdue representatives sought creative ways to enforce older guidelines. They quizzed doctors on the AHCPR guidelines, "establishing the federal guidelines as the *Standards of Care* for cancer pain management" and making doctors members of "The Pain Team." PKY180242433.

Purdue representatives would then “transform the ‘Big Picture’ to a personal level” by “showing the Federal Guidelines information is being incorporated into the survey evaluation process for JCAHO (Joint Commission on the Accreditation of Healthcare organizations).” The implication of the “personal,” is that the doctor could get in trouble for undertreating pain. “Talking about their personal role in patients care and the practical application of the Federal Guidelines recommendations usually leads to a discussion of a patient they currently have under their care. At this point the Purdue Frederick sales representative is transformed into a Pain Management Consultant.” *Id.*

On November 12, 1999, Janssen sent a bulletin out to its sales force about a report in the *British Medical Journal* of a doctor being disciplined for undertreating pain. JAN-MS-02728546. “One of the issues that is driving the rapid expansion of the pain market is the changing attitude towards the treatment of chronic, severe pain.” JAN-MS-02728546.

The Robert Wood Johnson Foundation (“RWJF”) funded the Joint Commission to develop pain standards in collaboration with the University of Wisconsin-Madison School of Medicine (Pain & Policy Studies Group) “and experts from around the country.” JAN-MS-02728546. Those standards would go into effect in 2001. The Robert Wood Johnson Foundation also funded creation and dissemination of the Model State Guidelines through the Federation of State Medical Boards. PDD1706042217. It also funded the Pain & Policy Studies Group. PDD180550457. Dr. Payne’s resume shows substantial overlap between RWJF and Janssen advisory boards. JAN-MS-00402671.

The RWJF currently owns nearly \$2 billion in J&J common stock, and the organization has been funded from its inception (at least in part) from that stock grant.²⁸

²⁸ <https://www.rwjf.org/content/dam/files/rwjf-web-files/Financials/FY2017-RobertWoodJohnsonFdn-FS.pdf>

Around July 1997, an unidentified Purdue employee wrote an internal memo regarding the need for consensus guidelines on the treatment of non-malignant pain. PKY181320029; PKY183033731. The memo references a Janssen study in Business and Health as demonstrating undertreatment of pain and suggests creating the guidelines to distribute to Purdue's "core audience involved in non-malignant pain management." PKY183033731.

By 1998, Purdue had thought leaders teaching CMEs on "Defining New Standards of Care" through the University of Wisconsin Medical School (Pain & Policy Studies Group), which was currently working on the JCAHO standards. PKY180947825. At least one of the thought leaders, Cohen, disclosed that he received funding from both Janssen and Purdue. PKY180947825.

By late August of 1998, Purdue drafted out its plan to influence pain treatment guidelines disseminated by state medical boards – and recorded that plan in a memo. See PKY183033795. An early version of the memo records that "some physicians have stated that not relieving pain optimally is tantamount to moral and legal malpractice." PKY183028056 at -56. The memo focuses on barriers to using opioids in non-cancer pain, identifying those barriers as 1) burdensome state laws and regulations, 2) inadequate training of providers, 3) provider concerns of addiction and investigation, 4) societal attitudes, and poor coordination among policy makers, consumer groups, purchasers, and health care providers. PKY183028056 at -56-57. "Toward this end, the Federation of State Medical Boards has drafted model guidelines for prescribers, which the federation hopes will be adopted universally. Pain policy analysts we spoke with argue that a non-legislative approach to affecting change (*i.e.*, adopting practice guidelines) is better than a legislative approach because guidelines are easily modified as the practice of pain management changes." PKY183028056 at -58.

The early version of the memo discusses "opportunities" and cites "independent research organizations" who study pain and policy: the Midwest Bioethics Institute and the Pain & Policy

Studies Group. *Id.* The memo says that the groups' large research projects have been funded largely through the Robert Wood Johnson Foundation; it gives one example of an \$11.25M program, Community-State Partnerships to Improve End-of-Life Care, though which grant applicants are advised to include in their proposals plans to "develop and disseminate guidelines that promote effective pain management." *Id.* 47 of 50 states submitted programs. PKY183033795 at -98.

The Purdue guidelines memo eventually became a formal Partners Against Pain booklet titled "Fostering Change in the Pain Management Environment," Purdue worked on the project through Fleishman-Hillard, Inc., a public relations firm. PKY183028056. Program objectives: "Strategically foster public policy changes in the use of opioids for pain management. Impact the prescribing environment in which opioids are used for responsible pain management. Position Purdue Pharma with key stakeholders in a manner that will be helpful to future product launches." *Id.* at PKY183033795 at -99. The memo determines that the most impact can be had on the state level, and it identifies specific states to start with. *Id.* at -03.

"This plan will support existing state efforts, such as The Robert Wood Johnson Foundation's Community-State Partnership Program, which will put tremendous dollars and influence behind reworking pain management guidelines and legislation. Our preliminary assessment is that this program presents opportunities for alliance building for Purdue Pharma." *Id.* Purdue then produced the brochure titled "The Seven Myths of Pain Management" that it disseminated as an educational piece for "decision-makers, opinion shapers and consumers." *Id.* at 00.

Purdue and Janssen had tactical meeting around October 13, 1998, bringing leadership and sales representatives together to discuss Ultram SR business plans. JAN-MS-00270848. Purdue and Janssen met again in November 10, 1998 to discuss abuse liability for Ultram SR in relation

to their NDA submission to the FDA. JAN-MS-01051749. The companies continued working together at least through January of 1999 to address clinical trial issues. JAN-MS-01051770.

Around the same time, a PowerPoint presented by the R.W. Johnson Pharmaceutical Research Institute, J&J's umbrella research subsidiary advocates for the development of pain treatment guidelines across the spectrum of painful conditions, as well as pain management conference and a coordinated education program for physicians, insurers, and patient advocacy groups. JAN-MS-01003804; *see also* JAN-MS-02759375, JAN-MS-00456512, JAN-MS-02727945. Janssen believed guidelines were "underutilized." JAN-MS-02727943. It is also around this time that Janssen begins considering combining J&J's pain franchise, currently split between Janssen, Ortho-McNeil, and Pri-Cara. JAN-MS-02727943.

On December 1, 1998, Janssen met with the AGS board of directors to discuss updating the new AGS guidelines. JAN-MS-00270846.

In December 1998, Purdue was already anticipating using the JCAHO guidelines to sell – before the guidelines were published. Production reveals a JCAHO "compliance kit" on making pain management appropriate for all patients, not just the dying. PKY18122672.

By February of 1999, Purdue sought to partner with the VA and APS on the "Pain: The 5th Vital Sign" campaign. PKY183036326. Purdue planned to "[e]xtend base of support to states via VA network, state medical boards, or managed care organizations." PKY183036326. at -26. At the time, Purdue already envisioned a consensus statement from APS and AAPM as part of the plan, intending to pass out the guidelines and consensus statements at CME programs. PKY183036326. at -28. "Foster changes in pain management through educational seminars directed at physicians and thought leaders . . ." PKY183036326. at -27.

Initially, Purdue intended to target ten states, those with the best business development opportunities. PKY183036326. at -26. This was accomplished through Fleishman-Hillard and

Lyons Lavey Nickel Swift, Inc. *Id.* On August 11, 1999, an internal email asked how to get “mileage” from a New York Times article about pain killers and new guidelines. PPLPC012000005648. The response was that Purdue should put together programs based on its experience in California, Nevada, and Ohio. PPLPC012000005648. “If we can get the governing board’s message out, it can only help us sell more.” PPLPC012000005648. By March of 2001, a Janssen consultant, Discovery International, recommends targeting the state medical boards to expand the FSMB 1998 Model Guidelines, as well as breaking down the JCAHO guidelines to make them more easily accessible to doctors. JAN-MS-003131999 at -01 By 1999 Purdue sent an employee to speak with “key JCAHO players” about Purdue’s interests. PDD1701879922.

In June 2000, evidence links Purdue and RWJF. PPLPC029000018652. The parties intended to meet to discuss how to partner with RWJF’s “Last Acts” campaign. PPLPC029000018652. Michael Friedman and Robert Reder attended the meeting, and potentially Haddox. PPLPC029000018652.

In September 2000 a Purdue publication titled “Preparing for JCAHO: Implications for the Case Manager” stated: “In 2001, for the first time, all JCAHO-accredited institutions and organizations will be expected to demonstrate their ability to assess and manage pain in all patients, not just in the final days of life, but across the continuum of care.” PDD8801316960. JCAHO education materials became standard for Janssen representatives by November of the same year. JAN-MS-02327808.

Then, in November of 2000, several companies cooperated with the NPC and JCAHO to disseminate the new guidelines. JAN-MS-00654711; JAN-MS-00654707-11. On November 28, 2000, Jeann Gillespie from the NPC emailed employees from Janssen, Knoll, AstraZeneca, Abbott, Pfizer, BMS, Merck, and, curiously, Monsanto to inform them that the JCAHO “pain management project” is moving forward. JAN-MS-00654711. Through the project, NPC and

JCAHO intended to produce pain management monographs with a prestigious editorial advisory board; Gillespie asked for recommendations, suggestions, and comments. JAN-MS-00654711. She also promised to send out invoices and logistics for the companies' financial commitments. JAN-MS-00654711.

On December 8, 2000, Bruce Moskowitz sends Gary Vorsanger an email about the NPC JCAHO project, attaching an update and notes from an October 19 call. JAN-MS-00654707. JAN-MS-00654709. The parties discussed educational monographs on pain treatment to "raise awareness and identify gaps." JAN-MS-00654709. "This approach is high level and non-drug specific, which is essential for collaboration." JAN-MS-00654709. An expert panel and monographs were proposed, with the panel to include "leaders and stakeholders that have experience in measuring and improving compliance with pain management guidelines." JAN-MS-00654710. In the meeting, Dave Kerr from Knoll discussed sponsoring two pain-management summits with Purdue. JAN-MS-00654709. A \$50,000 investment was requested from each company. JAN-MS-00654709.

The Defendants had input on the monographs. On April 1, 2001, Moskowitz sent a draft of the Pain Management Monograph from the NPC to an employee to "determine whether any treatment guidelines that include OxyContin and Duragesic are appropriately addressed." JAN-MS-00655132. This is not the only time that Janssen would look out for the interest of Schedule II drugs as a class, not just Duragesic, as further described below. The final manuscript is attached to JAN-MS-02336600, and Vorsanger says he thinks it will be useful for marketing. Janssen intended to give it to "customers who ask about pain management." JAN-MS-02336678. Janssen, and all of the involved companies, received 5,000 copies of the monographs. JAN-MS-02109392.

Ohio reps were taking the “5th Vital Sign” (JCAHO guidelines) message to doctors, saying, “It cannot be ignored.” JAN-MS-00306718. Telling reps to give doctors a pain contract if they are concerned about treating with opioids, and to do speakers programs to address substance abuse.

In 2002, Purdue internally discussed Janssen’s product growth, saying that growth “require[s] unique tactics such as JACHO and similar programs.” PLPC009000079874.

In April of 2016, JCAHO would release a statement on “misconceptions” surrounding the 2001 JCAHO guidelines. https://www.jointcommission.org/joint_commission_statement_on_pain_management/. Those misconceptions include:

1. The Joint Commission endorses pain as a vital sign.
2. The Joint Commission requires pain assessment for all patients.
3. The Joint Commission requires that pain be treated until the pain score reaches zero.
4. The Joint Commission pain standards caused a sharp rise in opioid prescriptions.

The University of Wisconsin’s Pain & Policy Studies Group

The Pain and Policy Studies Group, out of the University of Wisconsin, played an important role in the 2001 JCAHO guidelines. The primary individuals associated with the group are June Dahl and David Joranson.

A Milwaukee newspaper interviewed Dahl and summarized the PPSG and market expansion story:

The analytical Dahl — who, at 84, is among the oldest active Wisconsin professors — reflects, then says candidly: “It appears that the promotion of better pain management has led to more liberalization of the prescribing of opioids, which has led to an increase in the availability of the drugs, which has led to some people abusing them, and then, when they can’t get pills, to heroin as criminals promoted it.”

http://www.gmtoday.com/news/local_stories/2014/heroin-special/09102014-uw-madison-researchers-played-role-in-increasing-opioid-use.asp. Dahl told the paper that pain policy “needed

a stick,” so “Dahl (with Robert Wood Johnson funding) began encouraging the Joint Commission, which accredits most American hospitals and doctors’ offices, to adopt new pain assessment standards.” *Id.* Once JCAHO adopted the new standards, doctors and hospitals would be accountable for undertreating pain.

The Robert Wood Johnson Foundation funded the Pain & Policy Studies Group. PDD180550457; WIS_PPSG_002971; WIS_PPSG_010253; WIS_PPSG_011735. Janssen gave it startup money. CITE. PPSG members, RWJF, and Purdue communicated closely. WIS_PPSG_000511; PPLPC029000018652. Robert Wood Johnson Foundation also funded creation and dissemination of the Model State Guidelines through the Federation of State Medical Boards. PDD1706042217. Dahl was also on Janssen’s NPEC board.

Beginning in 1997, Purdue and Janssen (through Ortho-McNeil) co-promoted Ultram SR. PPLPC018000002278; PKY181968431, JAN-MS-00456519. A letter from a Purdue employee to Michael Friedman recounts how Ortho McNeil worked with the FDA to ensure that Ultram was kept at a lower schedule level – and created what was perhaps the first industry/government addiction monitoring program. PKY181424209. The letter says that Ortho McNeil had Dr. Sydney Schnoll convened a group of addiction specialists at McNeil corporate headquarters to discuss how to persuade the FDA to consider a lower schedule. Ultimately they put in place a “program where the responsibility for monitoring potential abuse problems would be shared by both government and the manufacturing organization.” PKY181424209. “The work of Dr. Schnoll’s group ultimately contributed to the non-scheduled status of Ultram.” PKY181424209. “Even though Ultram in long term use anecdotally is known to cause dependence and in some causes addiction problems, when these troubles do occur McNeil is usually the first to know about them and is able to take appropriate action to resolve the problem.” PKY181424209. The Purdue employee says this is made possible through a database that monitors prescriptions.

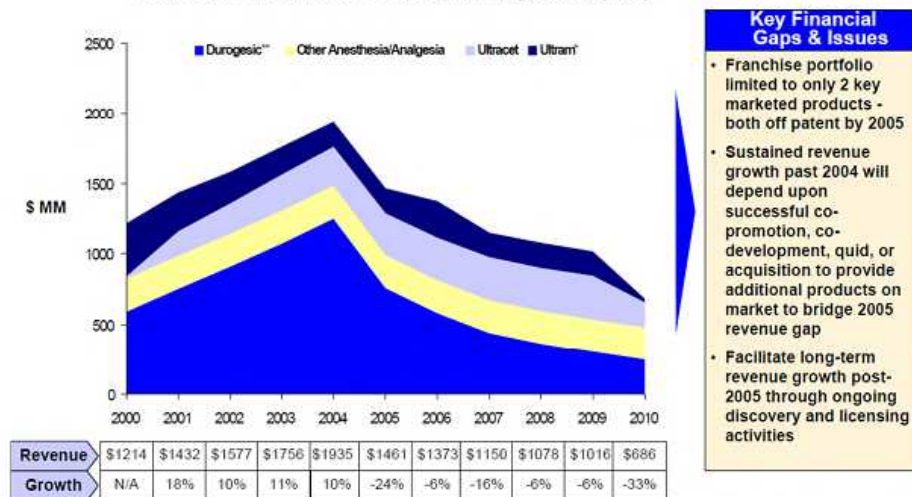
This is corroborated by Friedman's notes from the April 1997 Ultram meeting between Purdue and Ortho McNeil. PPLPC018000002278.

By May of 2000, Janssen was aware that it had a "gap problem" for the year 2005. As of that time, Janssen through Ultram and Duragesic controlled 11% of the pain and inflammation market, a share valued at \$1.3 billion to the company. JAN-MS-00456087. But without new drugs or expansion of the product base, that share drops to \$686 million by 2010, with a steep decline at 2005 before new products could be introduced. JAN-MS-00456087 at 25.

PAIN AND INFLAMMATION FRANCHISE - Internal Gap / Opportunity Analysis P - SM

Financial Projections and Growth

Franchise 10-Year Revenue & Growth Projections (WW)



Source: Portfolio forecasts. *Ultram includes Ultram & Ultram SR. **Duragesic includes Duragesic, Duragesic 12.5, & Duragesic Matrix
JJPG Confidential

Pain & Inflammation
Franchise Plan 25

Janssen knew that opioid use is increasing because of improved perception of health care policy stakeholders, specifically the WHO and NIH. JAN-MS-00456087. "Demand exists for products that offer the efficacy of opioids but do not have the associated side effects or addiction potential." JAN-MS-00456087. Janssen apparently intended to invest up to \$80M in Ultracet and

Duragesic DTC marketing, recognizing the potential in non-cancer pain and “under-treated groups.” JAN-MS-00456087. At this time, the Janssen US sales force viewed Duragesic as second detail, and there was no Janssen primary sales force for analgesia in US. JAN-MS-00456087.

Thus, Janssen began looking for a co-development project by year end 2000. “Increased industry reliance on partnerships poses both opportunities and competitive threats.” JAN-MS-00456087. The top-line recommendation: co-promote and co-develop to pursue 2005 revenue potential. JAN-MS-00456087.

At the same time, Purdue’s sales of OxyContin were just beginning to pull ahead of Janssen’s sales of Duragesic. JAN-MS-00615319. By 1997, Purdue was anticipating a generic of MS Contin, and “one of the primary objectives is to capture patients who would have been started on MS Contin to OxyContin, as quickly as possible.” PKY183222319 at -25. Janssen has been targeting the moderate to moderately-severe market for the past two to three years but making slow progress. PKY183222319. Janssen spent over \$1M in 1996, through August, advertising in Journals to target internists and PCPs (as opposed to pain specialists).

In April of 1994, Purdue commissioned Strategic and Tactical Recommendations for OxyContin’s 1996 launch; at that time, the recommendation was to position OxyContin to treat cancer pain. PKY180287212 at -13. But from the outset, Purdue intended to expand into non-cancer pain. PKY180287212 at -35. However, it appears from the Strategic and Tactical Recommendations that such an expansion would have to occur *after* the launch in cancer pain. PKY180287212 at -35. By 1998, the OxyContin budget included a plan to “enhance the acceptance of opioids for non-cancer pain.” PKY180233846 at -60. The plan was to “attach an emotional aspect to non-cancer pain so physicians treat it more seriously and aggressively.

PKY180233846. “The positive use of opioids, and OxyContin Tablets in particular, will be emphasized.” PKY180233846 at -63.

On March 20, 2000, Janssen’s Global Commercial Team (“GCT”) met to discuss objectives. JAN-MS-00478443. Among them was moving the position of Duragesic from Step 3 (“mostly cancer pain”) of the WHO pain ladder to Step 2 (“opioids-non opioids, for chronic pain overall in opioid naïve patients”) of the pain ladder. JAN-MS-00478443. The GCT expressed intent to build a “spine” for the overall commercial development, publication, and communication strategy, saying “[w]e must be the champion to insure maximal support at the OC level to grow Duragesic above the \$1 billion level before 2003.” JAN-MS-00478443. In furtherance of the scheme, Defendants convened a panel of experts in Rome to gather information for marketing Duragesic. JAN-MS-00478453. Noted was consensus that “high quality evidence to support the use of DUROGESIC in chronic non-cancer pain is required, particularly from long term studies.” JAN-MS-00478453 at 2, 4, 6; JAN-MS-00478471.

Later, a February 16, 2000 email confirms a March 17, 2000, four-hour meeting between Janssen and Purdue. JAN-MS-0246903. On the agenda are Janssen’s current pain audience, Ortho-McNeil’s current pain audience, Purdue analysis, co-promotion options, and next steps. JAN-MS-0246903.

This meeting was discussed at the Janssen Global Commercial Team level because March 20, 2000 Janssen GCT meeting notes says, “VC to deliver extensive buprenorphine competitive assessment to next GCT meeting (sales forces, claims etc.) Other product mentioned: OxyContin and Palladone.” JAN-MS-00478443 at -45.

By May 2000, Janssen had created plans to present to Purdue, including a plan to co-promote OxyContin. JAN-MS-01052181. “Project Objective/Rationale: Build a partnership between Purdue Pharma LP and J&J that leverages each partner’s assets and capabilities to create

a Pan Management Franchise that is significantly larger and more profitable than that which the partners could build on their own.” JAN-MS-01052181.

A Powerful Combination

J&J

- Sales/Marketing
- Tylenol & Motrin
- Duragesic
- Ultram/Ultram SR
- Ultracet
- Intellectual property
- R&D pipeline and capabilities

Purdue

- Sales/Marketing
 - Oxycontin
 - MS Contin
 - Ultram SR
 - Palladone
 - Intellectual property
 - R&D pipeline and capabilities
-

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Business Development

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11/13/2018

Internally, the plan was called “Project Pearl.” JAN-MS-01051754. Janssen and Purdue were scheduled to meet again for a discussion about partnership alternatives on September 6, 2000. JAN-MS-01051754. Janssen internally discussed three options: Reciprocal co-promotion rights on all brands, R&D partnership for development of new brands, Joint Venture to create stand-alone pain company. JAN-MS-01051754. Janssen determined ultimately to present the reciprocal co-promotion idea, with a financial structure that revenue and profit split on all brands, J&J heavier on revenue and Purdue heavier on profit. JAN-MS-01051754. A J&J “next step” was to develop a “one Pain Sales force” configuration for J&J and the company began internally restructuring

around this time. Likewise, a June 9, 2000, PPT slide depicts Janssen's analgesic pain spectrum portfolio including OxyContin. JAN-MS-00785194.

A July 28, 2000 email from Michael Grissinger to several others at Janssen discusses the impending September meeting with Purdue to "explore ways in which we might work together in pain management." JAN-MS-01052165. Grissinger asks that the information be kept confidential. JAN-MS-01052165.

A PowerPoint envisioning mirrored sales forces, with all reps carrying both companies' products appears to be what Janssen presented at the September meeting. JAN-MS-00311050.

Potential Purdue/J&J Pain Mgt Sales Force Deploymen

- Mirror Purdue and Janssen sales force
 - Combo territory
 - Fewer JNJ reps needed
- All 5 pain products carried by all representatives
- Rotation of products would develop on 3- to 4-month cycles according to need.

	Purdue N = 700	JNJ N = 700
Primary Care	OxyContin/Palidon Ultracet/SR/DURAGESIC®	Ultracet/SR/DURAGESIC® OxyContin/Palidon
Pain Specialists	OxyContin/Palidon Ultracet/SR/DURAGESIC®	Ultracet/SR/DURAGESIC® OxyContin/Palidon
All other HVPs	OxyContin/Palidon Ultracet/SR/DURAGESIC®	Ultracet/SR/DURAGESIC® OxyContin/Palidon

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11/13/2018

A later, November 2000 PPT shows Janssen discussing co-promotion opportunities with Knoll and, curiously, that PPT shows the imagined Janssen/Purdue sales force as part of the deal, per below. JAN-MS-00456095.

Proposed Knoll/ J&J Deployment

- Mirror Knoll and J&J sales forces
 - Combo territories
 - Sales representatives will be trained in all 5 products but carry 3
- Four sales forces of 350 representatives--2 each from Purdue and J&J
 - Allows for maximum flexibility to deliver 5 products in priority position
 - Each sales force can reach 60,000 physicians individually
 - Frequency goals attained by overlapping of physicians
 - 2.02 million primary positions with 3.23 million PDEs to allocate
- Product priorities will be developed on 3- to 4-month cycles according to need

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Business Development

7

11/30/2018

Finally, a January 3, 2001 PPT about co-promotional opportunities mentions Purdue Frederick: "Reviewing how we can work together to help each company achieve maximum sales potential of existing and future products." JAN-MS-00456093.



Co-Promotional Opportunities

- **PURDUE FREDERICK**
 - Reviewing how we can work together to help each company achieve maximum sales potential of existing and future products
 - Purdue and OMP marketing teams plan to meet to discuss the options to work together.
 - Janssen also needs to be involved in these discussions

Janssen acted to protect *all* Schedule II drugs, including OxyContin. On April 20, 2001, Bruce Colligen at Janssen sent an email to Dennis Fitzgerald and others regarding “[t]he OxyContin issue” JAN-MS-00307337. The email worries that state legislatures are responding and suggests drafting legislative language that Janssen’s lobbyists can use “to protect J&J business interest.” JAN-MS-00307337. “We want to be certain that Janssen (Duragesic) does not get caught in the OxyContin web, but we also need to have enough foresight to look towards the future of pain management and not be too limiting.” JAN-MS-00307337. “It is not our policy to advance language that would attack a competitor’s product.” JAN-MS-00307337. The email also acknowledges that the company has fought the issue of triplicate prescription pads and has been successful over the years. JAN-MS-00307337. Abuse issues “make our job more difficult.”

Id. An April 22, 2001 S.W.O.T. Analysis says that the abuse discussion can damage the total market. JAN-MS-00478511

Purdue sent a letter to its entire sales force on April 2, 2000, telling its representatives not to sell OxyContin by talking to doctors about the potential for Duragesic abuse. PKY182107687. “Janssen Pharmaceuticals and Purdue have agreed that should either company have representatives who promote product out of label or out of policy, the name of the representative will be provided to the other company for investigation and disciplinary action if necessary.” PKY182107687. Indeed, Friedman and Norton/Gorsky spoke and wrote directly about the issue. PKY181022850; PPLPC009000036199; PKY181103719.

On August 14, 2001, Dennis Fitzgerald, Jim Eckhard, Steve Huber, David Duvall, and Ed Rady and others at Janssen met regarding OxyContin abuse issues to be discussed in front of the FDA advisory board. JAN-MS-00899138. In particular, the group was concerned about whether to get involved in the public debate. “On the plus side, [getting involved] allows us to take a position, not rely on PF [Purdue], and to acknowledge that we are already ‘involved’ by virtue of the product we market.” JAN-MS-00786155. “On the negative side, we will not be involved, we risk getting ‘linked’ with Oxycontin, and we will need to support our position.” JAN-MS-00786155. They decide to take an active role. They intend to reach out to John Coleman at the DEA to ask him to submit DAWN database analysis in writing. They say they should either “protect the class [which would include Oxy] from restrictive actions,” actively differentiate Duragesic as less abuse potential, or simply “leaving out our opinions (good and bad) on the use of the class”

The notes later get edited, and the editor suggests, “Advocate for aggressive treatment of pain, defend the class and ‘mention’ that there are multiple types and formulations of opioids, which have different safety/benefit profiles –including . . . Duragesic The key is not to turn

this into a promotional platform (especially since I don't think we have enough data to back up our 'less-abuse-prone' claim." JAN-MS-00899138.

Gary Vorsanger of Janssen would make a three-minute presentation to the FDA. Discovery International, a consulting group, helped to draft the message. "It was suggested that KOLs have a limited awareness as to the scope of the problem; therefore it would be advantageous to prepare a document that follows the story (in the press) over time." JAN-MS-00899138. Janssen internally admitted that its "experts" are not informed on abuse issues.

The next day, a Duragesic Tactical Plan seeks to create the NPEC, to expand further into the non-malignant pain market, to position Duragesic as the first opioid of choice, to "generate" a call to action among patients. JAN-MS-00306713. "Deliver a strong value story for long acting opioids in general and Duragesic specifically." JAN-MS-00306713. This evidences intent to grow the market for OxyContin – after the potential for abuse is understood.

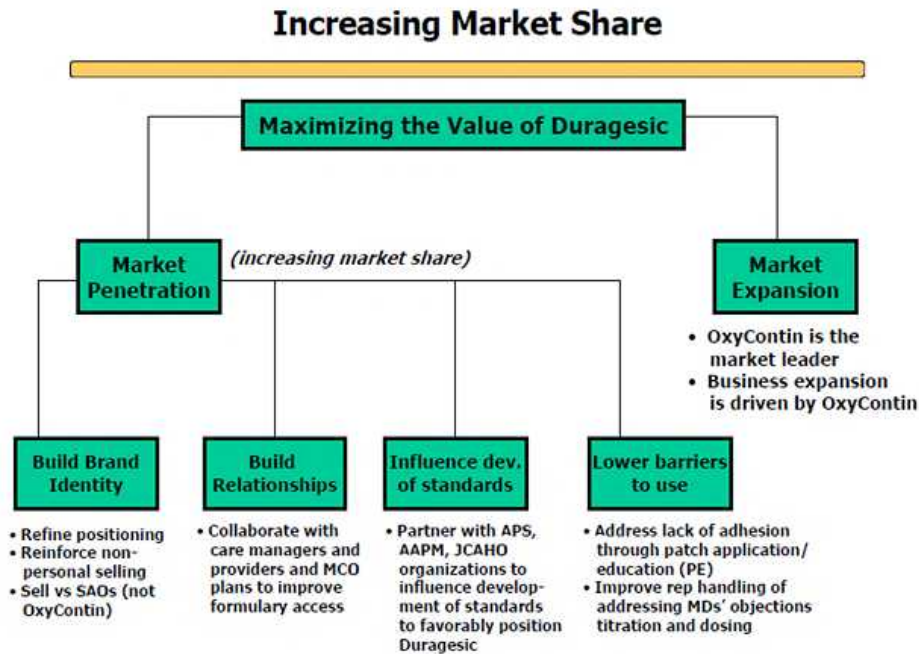
In April of 2001, Purdue created a Partners Against Pain Advocacy Toolkit, essentially a guide to how to control the abuse message, and Janssen ended up with a copy. JAN-MS-00304077.

Purdue and Janssen also had contact through the "Pain Forum" meetings. In October 2002, a save the date for "Pain Forum II" meeting of DEA and industry leaders was sent out. JAN-MS-00386260; JAN-MS-00614872. The meeting was organized by Joranson of the Pain & Policy Studies Group and by Last Acts (RWJF). And in the summer of 2001, the DEA & Joranson had meetings with "select industry members" on OxyContin abuse issues, which resulted in the DEA consensus statement. JAN-MS-00386260.

"The chronic pain market has vastly expanded because of two primary players, Duragesic and Oxycontin." JAN-MS-00299220.

Janssen acknowledges that Oxycontin drives market growth, generally, and drives Duragesic growth, specifically. JAN-MS-00306767; JAN-MS-00299220; JAN-MS-00432716

(Kuntz). Janssen sought to drive patients & prescribers from short-acting opioids to long-acting opioids, like Duragesic. JAN-MS-00494171 at 14 (Moskovitz).

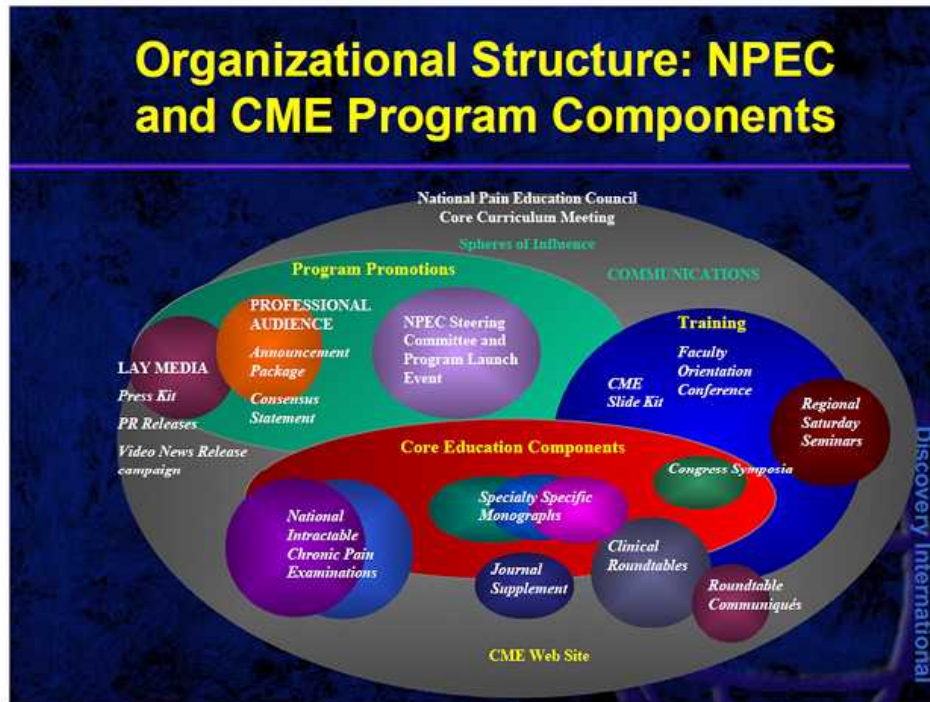


On November 11, 2001, Jeff Mathis wrote that "Oxycontin and Duragesic are responsible for growth [of the Strong Opioid Market]." JAN-MS-02531371. He placed growth at 21%. "Growth of OxyContin was only slowed by concerns over the abuse potential." JAN-MS-02531371. In another document created by McKinsey & Company for Janssen's Global Operations Team on Duragesic Disease Modeling, acknowledging that OxyContin created the market in low back pain, which is where Duragesic wants to position itself. JAN-MS-00432716 at 4. A Janssen request for research proposals tacitly acknowledges that competitor sales can expand the chronic pain market. JAN-MS-00305722. Further, a 2002 Duragesic business plan states that Purdue is an attractive co-promotion partner. JAN-MS-00310227 at -84.

Even when competing, Purdue recognized the companies helped each other: “We will produce and create programs that will generate interest and growth in Pain management, and so will [Janssen]. In some cases some of the things they do will help us, and vice-versa.” PPLPC009000079874.

Janssen spent millions creating the National Pain Education Council (“NPEC”) with the help of Discovery International (AKA: Discovery East, LLC) (“Discovery”) sometime around August 2001 as part of the Duragesic Tactical Plan. JAN-MS-00306713. According to an “Agency Performance Survey,” an internal review, Discovery became Janssen’s “medical education agency of record” in September 2000. JAN-MS-00781342. “The Discovery East team is dedicated to the overall management of the brand, not only execution of the actual tactics.” JAN-MS-00247190. Kathleen “Kati” Chupa, who looks to have been Discovery’s handler, deemed its programs “effective and aligned with brand strategies.” JAN-MS-00781342.

Janssen’s vision for the NPEC was comprehensive, as shown by the following slide:



JAN-MS-00306713. The organization was to be endorsed by APS, AAPM, and "other pertinent medical societies." JAN-MS-00306713. The timeline for the project can be found at JAN-MS-00314040.

Critically, the NPEC was to be (and was) co-chaired by Dr. Russell Portenoy (APS President) and Dr. Richard Payne, with numerous other doctors and a JCAHO representative sitting on its executive committee and peer review committee. JAN-MS-00306713. June Dahl of PPSG was also involved. According to January 2003 meeting notes, it appears that Drs. Payne and Portenoy were to be paid "\$15M" individually and "\$25M" to their respective institutions in honorarium. JAN-MS-00312977. The doctors also appear to have met with the DEA in their NPEC capacities. JAN-MS-00777576.

According to a Discovery presentation, its goals for NPEC were to:

- Drive healthcare providers to the NPEC website in 2002
- Initiate the positioning of the NPEC as the premier pain management education program for the medical community
- Position long-acting opioids as preferred therapy for the treatment of chronic pain
- Strengthen Janssen's positioning as a leader in pain management education

JAN-MS-00787624. A 2003 Tactical Plan shows the following NPEC Objectives:

- Establish website as a key educational resource for primary care physicians – specifically on the appropriate use of opioids for pain management
- Position as a referral site for pain specialists to encourage and facilitate education of the expanded pain management team
- Establish as an educational tool in fellowship and residency training programs
- Use as springboard for pain management franchise development
- Position Janssen as a leader in pain management

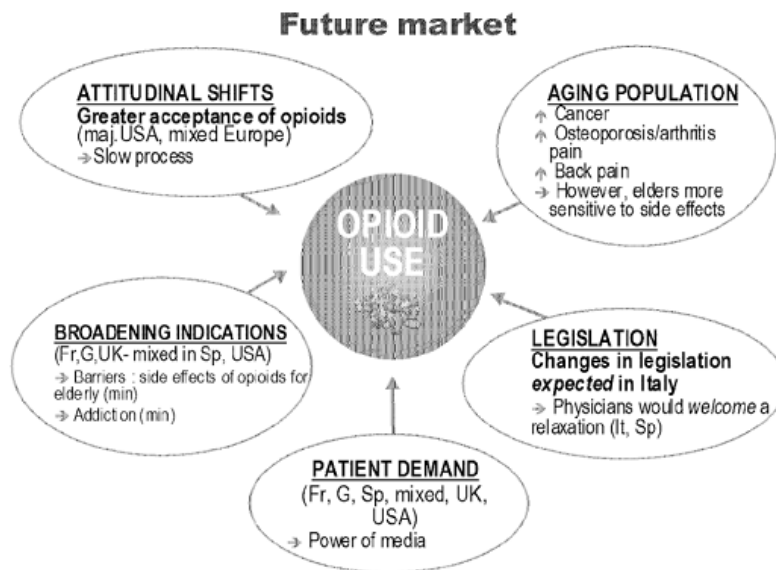
JAN-MS-00780331. An estimated budget for the year 2003 shows nearly \$10M on NPEC programs. JAN-MS-00306772.

Internally, the NPEC was certainly a top “strategy and tactic” for “position[ing] Duragesic as the optimal LAO choice for non-malignant and malignant pain.” JAN-MS-00494171 at 10-11. And Kati Chmonitorupa was clear that Discovery's work is one method of “leveraging Duragesic dollars for the franchise.” JAN-MS-00726338 (Blockinger).

A website, www.npecweb.org, was eventually created. See https://web.archive.org/web/*/http://npecweb.org/. Janssen disclosed that it funded the NPEC website, it also says that all content is created by the co-chairs. February 2002 meeting notes indicate that that materials for the NPEC program were “derived” from an outline written by Dr. Portenoy and Payne, approved by Discovery and reviewed by Janssen. JAN-MS-00312347. The same notes demonstrate that monographs were written by writers directed by Discovery. JAN-MS-00312347.

A July 2003 presentation lays out how Discovery assisted Janssen in promoting Duragesic

at APS, AAPM, and ASPMN symposiums. JAN-MS-02760144. Around the same time, other non-Discovery-related presentations clearly demonstrate that Janssen viewed attitudinal shifts and broadened indications, among other factors, as contributing to increased opioid use/sales:



JAN-MS-00371431 (2002 Taylor Nelson Sofres Report on Duragesic Lifecycle).

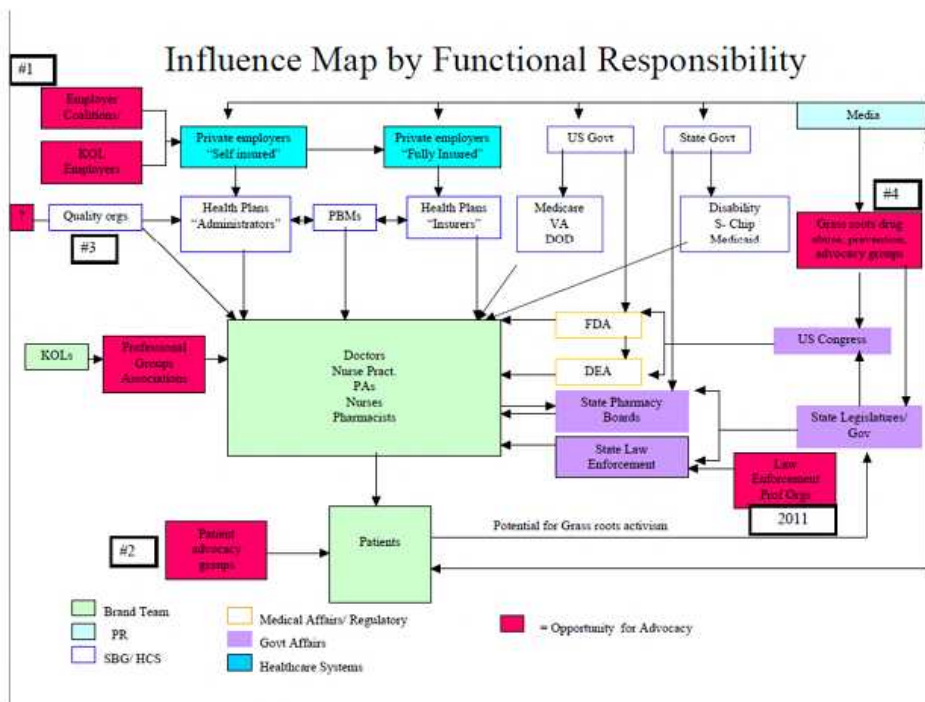


JAN-MS-00306755 (2001 Pain Franchise Review).

In June 2001, Janssen agreed to contribute \$50,000 to fund, with other manufacturers, an “Advanced Pain Management Certification Program” in Florida. JAN-MS-01144712. The program was targeted at pharmacists, and it was seen as a way to overcome their resistance to dispensing opioids. JAN-MS-01144712. The licensing program was viewed as “the first of its kind” and probable to “serve as a reference point for other such programs.” JAN-MS-01144712. In the same email, it is mentioned that the program is consistent with JCAHO objectives “i.e., fifth vital sign.” A 1997 survey funded by the Robert Wood Johnson Foundation that developed the pain 2001 JCAHO standards. David Baker, MD, MPH, *The Joint Commission's Pain Standards: Origins & Evolution*, THE JOINT COMMISSION (May 5, 2017), https://www.jointcommission.org/assets/1/6/Pain_Std_History_Web_Version_05122017.pdf.

See also JAN-MS-01144714.

From February 2009 AAPM Corporate Council meeting notes, it appears that Cassie Hallberg, Director of Analgesic Stakeholder Relations for Janssen (now a former employee) attended an AAPM meeting where she agreed to identify key professional and patient pain associations and to “map” out those stakeholders and lines of influence to each in order to help AAPM “start a movement.” JAN-MS-00929254. This occurred around the time the REMS Task Force was active. Cassie Hallberg created the “Influence Map,” below. JAN-MS-02494558.



Cassie also had the help of consultants from SmartAnalysis in gathering background data on all the organizational stakeholders. [JAN-MS-02494553](#).

Executive Summary
SMARTANALYST
INTELLIGENT INSIGHTS. SMART RESULTS.

Pain Association	Focus of Mission	Website	Newsletter	Geographic Presence	Number of Members
American Pain Society	High Focus on Pain Treatment <ul style="list-style-type: none"> To increase knowledge of pain and transform public policy and clinical practice to reduce pain-related suffering. 			National (six regional sections)	Over 3,000 (including health professionals, basic scientists, policy makers, and lawyers)
American Pain Foundation	High Focus on Pain Treatment <ul style="list-style-type: none"> To improve the quality of life of people with pain 			National	80,000 (including patients, families and healthcare providers)
American Chronic Pain Association	High Focus on Pain Treatment <ul style="list-style-type: none"> To facilitate peer support and education for individuals with chronic pain and their families. To raise awareness among the health care community, policy makers, and the public at large about issues of living with chronic pain. 			International (more than 800 chapters)	NA
American Academy of Pain Medicine	High Focus on Pain Treatment <ul style="list-style-type: none"> To advance the specialty of Pain Medicine and the comprehensive care of patients with pain. 			National (four state Chapters)	Over 1,300
Alliance of State Pain Initiatives	High Focus on Pain Treatment <ul style="list-style-type: none"> To ensure that peoples' lives are not overpowered by pain. 			National (19 state pain initiatives)	NA



Source: SmartAnalyst

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Cassie Hallberg also prepared a list of influential associations in each region of the country.

JAN-MS-02494558 (Kohn) (Central Region – others attached to JAN-MS-02494552).

Plaintiff reserves the right to supplement or amend its response, and this issue may be the subject of fully-supported and detailed expert witness opinion(s).

Dated: March 4, 2019

By: /s/ Linda Singer

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CERTIFICATE OF SERVICE

I, Richard Cashon certify that on March 4, 2019, I caused the foregoing to be served via electronic mail on Defendant's Liaison Counsel pursuant to the Case Management Order in this case (ECF #232).

/s/ Richard Cashon